EPA Jacket 54382-3 Vol.2

lease read instructions on reverse before completing form	Carel & marine &	Renalland A 3/9/3
United St Environmental Prote Washington, D	etion Agency Re	rgistration opp Identifier Number nendment
Appli	cation for Pesticide - Section I	
. Company/Product Number 54382-3	2. EPA Product Manager Akiva Abramovitch	2. Proposed Classification None Restricted
Company/Freduct (Name) atervet Inc./Taktic Emulsifiable Concentrate Miticide	/Insecticide 4	f toward toward
Name and Address of Applicant (Include ZIP Code) Intervet Inc. 29160 Intervet Lane Millsboro, DE 19966	(b)(l), my product is similar to:	accordance with FIFRA Section 3(c)(3) or identical in composition and labeling
X Check if this is a new address	Product Name	
	Section - II	
Amendment - Explain below. Resubmission in response to Agency latter dated X Notification - Explain below.	Final printed lebels in Agency letter dated "Me Too" Application Other - Explain below	NOTIFICATION MAR × 1 2005
8-10 and EPA regulations at 40 CFR 152.46 , and no other chan at it is a violation of 18 U.S.C. Sec. 1001 to willfully make any fa lotice 98-10 and 40 CFR 152.48, this product may be in violation	lee statement to EPA. I further understand that If this	notification is not consistent with the terms of PR
. Material This Product Will Be Packaged in:	380((0)) - 111	
Yes Yes No No No Street Packaging Visit Packaging Yes No	Yes No No per If "Yes" No per container	Type of Container Metal Pleatio Glese Paper Other (Specify)
Label Container		
Manner in Which Label is Affixed to Product	Lithograph Cther	
	Section - IV	
Contact Point (Complete items directly below for identif	fication of individual to be contacted, if necessa	ry, to process this applications).
White	Thie	Yelephone No. (Include Area Code)
Cor i sortify that the etatements I have made on this for) acknowledge that any knowlingly false or misleads both under applicable law.		end complete. • 6. Data Application
Signature	Senior Regulatory Affairs Specialist - F	hamacailleals
Typod Name ()	6. Date	
Varv K. Hagler	DR yough ST	

MAR 2 1 2005

Taktic[®]

EMULSIFIABLE CONCENTRATE MITICIDE/INSECTICIDE

FOR THE CONTROL OF TICKS, MANGE MITES AND LICE ON BEEF CATTLE, DAIRY CATTLE AND SWINE

DO NOT USE ON DOGS OR HORSES (MAY CAUSE FATAL COLON IMPACTION)

ACTIVE INGREDIENT:

Percent by Weight:

Amitraz

12.5

INERT INGREDIENTS:

<u>87.5</u> TOTAL 100.0

This product contains Petroleum Distillate.

EPA Reg. No. 54382-3

EPA Est. No. 264-CAN-001

U.S. Patent Nos. 3,781,355 and 3,864,497

USUARIO: Si usted no lee inglés, no use este producto hasta que la etiqueta haya sido explicada ampliamente.

(TO THE USER: If you cannot read English, do not use this product until the label has been fully explained to you.)

KEEP OUT OF REACH OF CHILDREN

DANGER-PELIGRO

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY
STATEMENTS

NOTICE: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

INTERVET INC. Millsboro, DE 19966 584300D

Product of Canada

NET CONTENTS: 760 ml (25.7 fl. oz.)

FIRST AID:

IF IF	Immediately call a poison control center or doctor.
SWALLOWED:	Do not induce vomiting unless told to do so by a poison control center or
İ	doctor.
	Do not give any liquid to the person.
	Do not give anything to an unconscious person.
IF IN EYES:	
	Remove contact lenses, if present, after the first 5 minutes, then continue
	rinsing.
	Call a poison control center or doctor for treatment advice.
IF ON SKIN:	Take off contaminated clothing.
	Rinse skin immediately with plenty of water for 15-20 minutes.
	Call a poison control center or doctor for treatment advice.
IF INHALED:	Move person to fresh air.
	If person is not breathing, call 911 or an ambulance, then give artificial
	respiration, preferably mouth-to mouth if possible.
	Call a poison control center or doctor for further treatment advice.
	For incidents involving HUMANS, call 1-800-228-5635, ext 132
	For incidents involving ANIMALS, call 1-800-345-4735, ext 104
Have the produ	uct container or label with you when calling a poison control center or doctor or
	going for treatment
NOTE TO PHYS	ICIAN: Amitraz, the active ingredient in this product, is a carbamate. Do not
use atropine as a	an antidote. Treat any overexposure symptomatically. Mucosal damage is
probable which in	ncreases the risk of gastric lavage. Contains petroleum distillate - vomiting may

PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animals)

DANGER

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- · Chemical-resistant apron or coveralls over long-sleaved shirt and long pants.
- · Chemical-resistant footwear plus socks.
- Chemical-resistant gioves.

cause aspiration pneumonia.

- Chemical-resistant headgear for overhead exposure.
- Goggles or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-vertitatett areas.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist of a washables, use detergent and hot water. Keep and wash PPE separately from affect laundry.

Age 2 of 5

08 March 2505

User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Store in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

In case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER.

CHEMICAL EMERGENCY PHONE NUMBER (SPILL, LEAK, FIRE OR EXPOSURE) 1-800-424-9300

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a	i manner inconsiste	nt with	its labeling
---	---------------------	---------	--------------

DO NOT USE ON HORSES or DOGS - CAN CAUSE DEATHS.

DO NOT OPEN CONTAINER UNTIL READY TO USE.

USE TAKTIC®E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SDIVENTS

Page 3 05 5

08 March 2002

BEEF AND DAIRY CATTLE

TAKTIC® E.C. can be used on lactating dairy animals, with no withholding period for milk following application. Also, there is no post-treatment staughter interval on beef and dairy cattle.

TICKS AND LICE:

TAKTIC® E.C. will control the following Ticks and Lice on cattle:

Lone Star Tick (Amblyomma americanum)

Gulf Coast Tick (A. maculatum)

Winter Tick (Dermacentor albipictus)

Brown Dog Tick (Rhipicephalus sanguineus)

American Dog Tick (D. variabilis)

Rocky Mountain Wood Tick (D. andersoni)

Spinose Ear Tick (Otobius megnini)

Black-legged Tick (Ixodes scapularis)

Tropical Bont Tick (A. variegatum)

Cayenne Tick (A. cajennense)

Cattle Tick (Boophilus annulatus)

Southern Cattle Tick (B. mlcroplus)

Biting Louse (Damajinia bovis)

Sucking Lice (Haematopinus eurystemus, Linognathus vituli, Solenopotes capillatus)

MITES

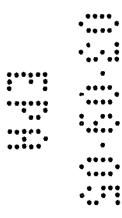
Scab and Mange Mites (Chorioptes bovis, Psoroptes ovis and Sarcoptes scablel var. bovis)

Spray:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. Use TAKTIC® solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Starticks, cattle ticks, sucking lice and chewing lice, particular attention should be given to the legs, axilla and groin area, udder, tail regions and head, including the ears. For Gulf Coast ticks and Ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice hatching from eggs.

Spray Dip Machine:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scables, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments 7-10 days apart are required to control cattle scables. Use TAKTIC® solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.



Page 4 Of 5

08 March 2005 5

SWINE

MANGE MITE AND LOUSE (Sarcoptes scablei var. suis and Haematopinus suis): IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use TAKTIC® solutions within 6 hours of mixing.

Spray:

Mix one can (760 ml) TAKTIC® E.C. in 50 gallons of water (equivalent to 1/2 fi. ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 psi is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jowi, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until runoff. A second treatment is recommended to break the parasites' life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pigs (piglets/weaners) is to dlp them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use TAKTIC® E.C. at the same time with any other Amltraz-containing product.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. INTERVET warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label. when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET and user assumes the risk of any such use. INTERVET MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET.

© 2002 INTERVET INC.

584350C MADE IN CANADA NET CONTENTS: 760 ml (25.7 fl. oz.)

08 March 2005

Page 50f 5



(302) 934-4340

08 March 2005

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202-4501

Dear EPA Notification Reviewer:

Please find enclosed a notification, per PR Notice 98-10, of minor label changes to the disclaimer statement for Taktic Emulsifiable Concentrate Miticide/Insecticide label (EPA Registration #: 54382-3; Intervet Inc., Company #: 54382). This notification is submitted in response to California Notice to Registrants 2004-3 which requires changes to the "Disclaimer" section of the label.

A completed EPA Form 8570-1 is enclosed as well as a copy of the proposed label. The proposed text to be removed is indicated by strikethrough and is also highlighted. In accordance with the PR notice, a stamped self-addressed envelope with note card identifying the notification and EPA Registration number is enclosed and we request confirmation of the acceptability of the proposed changes.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail (mary.hagler@intervet.com) should you have any questions.

Sincerely,

Mary K. Hagler, MS

Senior Regulatory Affairs Specialist – Pharmaceuticals

Intervet inc.

Enclosure

Jallo Intervet inc. •

Jallo Intervet inc. •

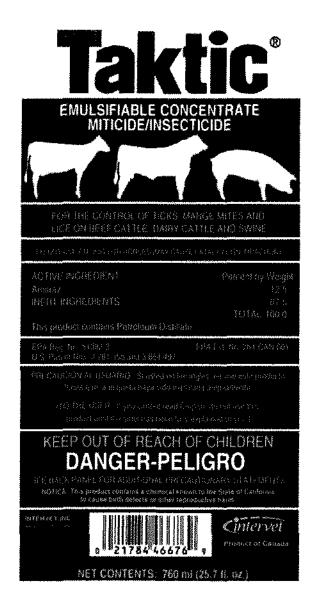
Jallo Intervet inc. •

P.O. Box 378 •

Lona Milsboro, DE 19966-0318

Tel. (302) 934-8051 FAX (302) 934-6087

	Farm.	Approved, OMB No. 2070	0-0080, Approval expires 2-28-
SEPA Environmental Protection Washington, DC 2	tion Agency	Registratio Amendme	F
Applica	tlon for Pesticide - Se	ction I	
1. Company/Product Numbet 54382-3	2. EPA Product M Akiva Abramov	-	3. Proposed Classification None Restricted
4. Company/Product (Name) Taktic Emulsifiable concentrate Miticide/insecticide	PM# 4		Total Total
5. Name and Address of Applicant Include ZIP Codel Intervet Inc. 405 State St. Millsboro, DE 19966 Check If this is a new address	(b)(i), my produc to:	et is similar or identical	with FIFRA Section 3(c)(3) In composition and labeling
	Section - II		
Amendment - Explain below. Resubmission in response to Agency latter deted Notification - Explain below.	Agency I	ated labels in repsonse to lotter dated Application.	28 August 2002
	Section - III		
Meterial This Product Will Be Packaged In: Child-Resistant Packaging Unit Packaging	Water Soluble Peckeging	2. Type of Cont	ainar
Yes Yes No	Yes No	Me Pie Gli	etal etic res per
prtification must be submitted If "Yes" Unit Peckeging wgt. No. per container	if "Yes" No. pe Package wgt conteil	·	her (Specify)
3. Location of Net Contents Information 4. Sizele) R	letell Container	5. Location of Label Di	rections
6. Menner in Which Label Is Affixed to Product	ograph Oti er glued colled	her	
	Section - IV		
1. Contact Point	tion of individual to be contacte	d, if necessary, to process	this application.)
Name Mary K. Hagler	Tide Regulatory Specialist - Pha		phone Ne. (Inciette Area Codel 2) 934-4340
Certific I certify that the statements (have made on this form or I scknowledge that any knowlingly false or misleading s both under applicable law.	nd all ettachmente thereto are ti		6. Date Application Received ••(Gtemped)
2. Signatura May K. Hagle	3. Title Regulatory Specialisi - Pharm	acouticals	
4. Typed Name Mary K. Haglet	5. Date 11 August	2003	••••



Va.

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated

AUG 28 2003



DESIGN LES

ematt gassd R	Sonation
IF IN EYES:	Thick eye open and thise stooky and gently with value for 15 20 transfer. Russome content lancese, if present, after the first 5 minutes, from contents internal contents or deserving tendence education.
IF ON SKRL	Takker off concentrated distraing Princip slide intranslatingly with planty of entire for 15-20 manufact Cell is possion restroit bander on denter for transfersor bufferse.
F MHALED:	 More person to inspiraze If person to not breaking, call \$1 if or an embedance, then give a relictal respiration protection protection from the mouth is possible. Call a possion control better to dictate for further inspiration advise.
1845 p.e. t	For Incoming Invalving INICAMES, and 1-86%-008-0088, and 152 For Incoming Invalving AMMALIA, and 1-86%-0034-075, and 1-94 resent compared or labor with your whom rathing a policion control committee or going for instituted.
an en articon T	RCLARI: Ambrill die active myrodynë in the product e a componise. Cie mai lies intojing mail any colonisticisum symmetrialistiky lakurises dumage is protekte inter introcesse the actie Componie posculierim dissilisse - vormony may status salprigon, prokumente.

PRECAUTIONARY STATEMENTS Hazards to Humans (and Domestic Animals) DANGER

Corresive. Causes irreversible eye damage. Causes skir intestion. Hamsfut it smallowed or absorbed through skin or shaded. Do not get in eyes, or skin or on clothing. Avoid breathing spray mist. Wear goggles or lace stield. Protonged trisquently represent skin contact may cause altergic insction in normal individuals. Weath throughly with soap and visitor after handling. Remove contaminated clothing and weath clothing before reuses.

- contamented between and water coloring before reuse.

 Personal Protective Equipment (PPE)
 Applicative and other handlers must wear.

 Chemical-resistant aprox or coveralls over long-elected shirt and long gents.

 Chemical-resistant flootweer plus socks.

 Chemical-resistant flootweer plus socks.

 Chemical-resistant flootweer plus socks.

 Chemical-resistant handlers for overhead orposure.

 Goggies or face shield; and chemical-resistant aprox when cleaning an increase.

ocupared, moving or loading.

Do not apply this product in a way that will contact workers or other persons, either diversity or through drift. Only protected handlers may be in the area during application.

in the area during expirication. For invisions price of pappications in enclosed areas: Apply only in well-verificated areas. Follow manufacturar's inseructions for cleaning/mentaining PPE. If no such instructions exist for washables, use detergent and hat werer. Keep and wash PPE separately from other taunchy.

- User Safety Recommendations

 Users should wash hands before seting, drinking, chewing gum, using
- Users should sent register security, britishing, drawing spire, wonly bibacco, or using the typic.
 Users should remove clothing immediately if persode gets inside. Then was if formighly and put on clean clothing.
 Users should remove Per immediately align handing this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pessible is fault to that and aquello invertibinates. Do not apply directly to water, or to areas where surface water is present or to intercidel onces below the most water mach. Do'th and surroll their brooked areas may be hazardous to aquello organisms in agreem sizes. Do not contaminate water when disposing of equipment washwater or massis.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open frame.

STORAGE AND DISPOSAL

STORAGE: Not for slowage in and around the home enrangement. Store in original container in a locked by place. Do not open the container until ready to use. Use entire contents of ozen when opened. Keep from freezing.

PESTICIDE DISPOSAL: Do not contaminate water, lood or foad by storage or disposer. Pesticide westes are toxic. Improper disposal of excess postoide, spray minture or rinsate is a volstion of federal law. If these wastes carnot be disposed of by use according to label instructions, confect your state pesticide or Environmental Control Agency, or the Hezerdous Waste representative of the nearest EPA Regional Office for guidance CONTAINER DISPOSAL: Triple rives (or equivalent). Then offer for recycling or reconditioning, or purcture and dispose of in a sanitary tandillis, or by other procedures approved by state and

In case of spillage, cover with an absorbert such as social ash, day or sawduel. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER. CHENICAL EMERGENCY PHONE NUMBER (SPILL, LEAK, FIRE OR EXPOSURE) (-800-424-9300

DIRECTIONS FOR USE

it is a violation of lederal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES or DOGS - CAN CAUSE DEATHS. DO NOT OPEN CONTAINER UNTIL READY TO USE. USE TAKTICS E.C. WITH WATER ONLT. DO NOT MIX WITH OIL OR DTHER SOLVENTS.

BEEF AND DAIRY CATTLE

7AKTIOD E.C. can be used on lectating delay entireds, with no washolding period for milk following application. Also, there is no post-treetment elsoghter interval on basil and dairy cards

TICKS AND LICE:

TAKTICS E.C. will control the following Ticks and Lice on caste: Lone Star Tick (Antisyonma emericanum) Gust Coast Tick (A. meculesum) Winter Tick (Dermacentor etripictus) Brown Oco Tick (Phipicophalus sanguiceus) American Dog Tick (D. verisbile) Rocky Mouman Wood Tyta (D. enderson) recent secretain rock (kt. ft. aroset Spinose Ear Tick (Otobias magnini) Black-legged Tick (floodes sospitaris) Tropical Bord Tick (A. vanegalum) Coyanne Tick (A. cajennerais) Cattle Tick (Boochika annulsaus) Southern Cattle Tick (B. necroplus) Billing Louisa (Damalinia bovis) Sucking Lite (Hisemalopinus euryalamus, Linogralmus vitus, Scienopores capitatus)

MITES

Scala and Mange Miles (Chorioptes bovis, Pacroptes ovis and Sarcoptes scalve ver, bovis)

Sexay: For control of ticks and Box, mix one can (760 mi) of TAKTIOS E.C. at 100 gallons of water, for control of males, max one can of TAKTICO E.C. in 50 gallons of water. Use TAKTICO solutions within 8 hours of mixing. Use up to 2 gallons of spray for a fully grown snime. It is important to well the arismal thoroughly and that

the spray panetrates to the skin unit run-oill. For Lone Star ticks, cense ticks, sucking lice and chaning lice, perfoular attention should be green to the lags, autia and groin area, udder, all regions and head, including the ears. For Guil Coast ticks and Ear ticks, treat the head, sera, excepted area and neck with a low pressure spray. For control of sice, a second treatment 10-14 days later is recommended to till see training from eggs.

Spray Dip Mechine:

For control of ticks and lice, mix one can (780 mi) of TAKTIOSE C. in 100 gallors of water, for control of mites, mix one can of TAKTION E.C. in 50 gallons of water. To control castle scattles, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments 7-10 days apart are required to control cattle acables. Use TAKTICO solutions within 6 hours of mixing. Use up to 2 gainers of epiny for a fully grown smires! It is important to well the anamal thoroughly and that the apray parastrates to the sion until non-cit.

SWINE

MANGE MITE AND LOUSE (Sancaptes scable) var. suis and Heamstopinus suis);

MAPORTANT

Pamore fised from pen and cover directly books. Remove and destroy bedding. Hose out lease and excess lead. Use TAKTIOS solutions within 6 hours of mixing.

Sorry:

Mix one can (760 mil) TAXTIOD E.C. in 50 gallons of water (agraination to 1/2 & ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 par is recommended. Spray the walls, floor and any fittings in the pen. Spray all aranges (at the same time) whether visitily attacted or not. Spray the animals until the mixture runs off, paying particular sharp an deliment was one manager hars on, paying paragram elsention to treat the joint, logs, inside the earn and underside of the body. It is important that the spray penetrates to the akin until un-cil. A second treatment is recommended to break the paraches the cycles. Adoks the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control,

An elternato lo epreying young pigs (piglote/wearers) is to do them in a substitute attest comisiner. Disp 30 animals and then recisce diswash. Use dip wash to treat premises.

Do not best svimsks more than 4 times per year.

Do not apply to swine water three days of elaughter

Do not use TAKTION E.C. at the same time with any other Amittazcontaining product.

@ 2002 PATERVET INC.

5843500 MADE IN CANADA NET CONTENTS: 760 ml [25.T R. cot.]



U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS 1200 Pennsylvania Ave., N.W. Washington, DC 20460-0001 EPA Reg. Number 54382-3

Date of Issuance AUG 28 2002

NOTICE OF PESTICIDE

Registration
X Reregistration
(under FIFRA, as amended)

Unconditional

Term of Issuance

Name of Pesticide Product
TAKTIC EC

Name and Address of Registrant (include ZIP Code):

Intervet Inc.

405 State Street

P.O. Box 318

Millsboro, DE 19966

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby reregistered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Registration is in no way to be construed as an endorsement or approval of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

Based on your response to the Amitraz Reregistration Eligibility Decision document, EPA has reregistered the product listed above. This action is taken under the authority of sec. 4(g)(2)(c) of FIFRA. Reregistration under this section does not eliminate the need for continued reassessment of pesticides. EPA may require submission of data any time to maintain the registration of your product.

The labeling submitted in connection with reregistration under the FIFRA is acceptable. A stamped copy of the draft label is enclosed for your records. Submit one (1) copy of your final printed labeling before you release the product for shipment. Should you have any questions, do not hesitate to contact Registration Review Manager, Dr. Akiva Abramovitch at 703-308-8328.

A Jaws

Signature of Approving Official:

Meredith Laws, Chief

Insecticide-Rodenticide Branch

Registration Division (7505C)

Date:

AUG 28 2002

EPA Form 8570-6



U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS 1200 Pennsylvania Ave., N.W. Washington, DC 20460-0001 EPA Reg. Number 54382-3

Date of Issuance AUG 28 2002

NOTICE OF PESTICIDE

Registration
X Reregistration
(under FIFRA, as amended)

Name of Pesticide Product
TAKTIC EC

Term of Issuance Unconditional

Name and Address of Registrant (include ZIP Code):

Intervet Inc.

405 State Street

P.O. Box 318

Millsboro, DE 19966

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On the basis of information furnished by the registrant, the above named pesticide is hereby reregistered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Registration is in no way to be construed as an endorsement or approval of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

Based on your response to the Amitraz Reregistration Eligibility Decision document, EPA has reregistered the product listed above. This action is taken under the authority of sec. 4(g)(2)(c) of FIFRA. Reregistration under this section does not eliminate the need for continued reassessment of pesticides. EPA may require submission of data any time to maintain the registration of your product.

The labeling submitted in connection with reregistration under the FIFRA is acceptable. A stamped copy of the draft label is enclosed for your records. Submit one (1) copy of your final printed labeling before you release the product for shipment. Should you have any questions, do not hesitate to contact Registration Review Manager, Dr. Akiva Abramovitch at 703-308-8328.

A Jaws

Signature of Approving Official:

Meredith Laws, Chief

Insecticide-Rodenticide Branch

Registration Division (7505C)

Date:

AUG 28 2002

EPA Form 8570-6

Taktic[®]

EMULSIFIABLE CONCENTRATE MITICIDE/INSECTICIDE

FOR THE CONTROL OF TICKS, MANGE MITES AND LICE ON BEEF CATTLE, DAIRY CATTLE AND SWINE

DO NOT USE ON DOGS OR HORSE (MAY CAUSED ATAL COLON IMPACTION)

ACTIVE INGREDIENT:

Amitraz

INERT INGREDIENTS:

AUG 28 2002

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide Traditional under Percent by Weight:

12.5

TOTAL 100.0

This product contains Petroleum Contains

EPA Reg. No. 54382-3

U.S. Patent Nos. 3,781,355 and 3,864,497

EPA Est. No. 264-CAN-001

PRECAUCION AL USUARIO: Si usted no lee inglés, no use este producto hasta que la etiqueta haya sido explicada ampliamente.

(TO THE USER: If you cannot read English, do not use this product until the label has been fully explained to you.)

KEEP OUT OF REACH OF CHILDREN

DANGER-PELIGRO

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

NOTICE: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

INTERVET INC. Millsboro, DE 19966 584300C

Product of Canada

NET CONTENTS: 760 ml (25.7 fl. oz.)

FIRST AID:

iF.	immediately call a poison control center or doctor.
SWALLOWED:	Do not induce vomiting unless told to do so by a poison control center or doctor.
	Do not give any liquid to the person.
	Do not give anything to an unconscious person.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes.
	Remove contact lenses, if present, after the first 5 minutes, then continue
	rinsing.
	Cail a poison control center or doctor for treatment advice.
IF ON SKIN:	Take off contaminated clothing.
	Rinse skin immediately with plenty of water for 15-20 minutes.
	Cail a poison control center or doctor for treatment advice.
FINHALED:	Move person to fresh air.
	If person is not breathing, call 911 or an ambulance, then give artificial
	respiration, preferably mouth-to mouth if possible.
	Call a poison control center or doctor for further treatment advice.
	For incidents involving HUMANS, call 1-800-228-5635, ext 132
	For incidents involving ANIMALS, call 1-800-345-4735, ext 104
Have the prod	uct container or label with you when calling a poison control center or doctor or going for treatment
use atropine as a	ICIAN: Amitraz, the active ingredient in this product, is a carbamate. Do not in antidote. Treat any overexposure symptomatically. Mucosai damage is ncreases the risk of gastric lavage. Contains petroleum distiliate – vomiting may

PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animais)

DANGER

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breething spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- · Chemical-resistant apron or coveralis over long-sleeved shirt and long pants.
- Chemicai-resistant footwear plus socks.
- Chemicai-resistant gioves.

cause aspiration pneumonia.

- · Chemical-resistant headgear for overhead exposure.
- Goggies or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

Follow menufacturer's instructions for cleaning/meintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.



User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Store in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a senitary landfill, or by other procedures approved by state and local authorities.

in case of splilage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER.

CHEMICAL EMERGENCY PHONE NUMBER (SPILL, LEAK, FIRE OR EXPOSURE)
1-800-424-9300

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES or DOGS -- CAN CAUSE DEATHS.

DO NOT OPEN CONTAINER UNTIL READY TO USE.
USE TAKTIC®E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS

BEEF AND DAIRY CATTLE

TAKTIC® E.C. can be used on lactating dairy animals, with no withholding period for milk following application. Also, there is no post-treatment slaughter interval on beef and dairy cattle.

TICKS AND LICE:

TAKTIC® E.C. will control the following Ticks and Lice on cattle:

Lone Star Tick (Amblyomma americanum)

Gulf Coast Tick (A. maculatum)

Winter Tick (Dermacentor albipictus)

Brown Dog Tick (Rhipicephalus sanguineus)

American Dog Tick (D.variabilis)

Rocky Mountain Wood Tick (D. andersoni)

Spinose Ear Tick (Otobius megnini)

Black-legged Tick (Ixodes scapularis)

Tropical Bont Tick (A. variegatum)

Cayenne Tick (A. cajannense)

Cattle Tick (Boophlius annulatus)

Southern Cattle Tick (B. micropius)

Biting Louse (Damalinia bovis)

Sucking Lice (Haematopinus eurystemus, Linognathus vituli, Solenopotes capillatus)

MITES

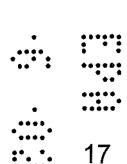
Scab and Mange Mites (Chorioptes bovis, Psoroptes ovis and Sarcoptes scablei var. bovis)

Spray:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. Use TAKTIC® solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Star ticks, cattle ticks, sucking lice and chewing lice, particular attention should be given to the legs, axilla and groin area, udder, tail regions and head, including the ears. For Guif Coast ticks and Ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice hatching from eggs.

Spray Dip Machine:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scables, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments 7-10 days apart are required to control cattle scables. **Use TAKTIC® solutions within 6 hours of mixing.** Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.



SWINE

MANGE MITE AND LOUSE (Sarcoptes scabiel var. suis and Haematopinus suis): IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use TAKTIC® solutions within 6 hours of mixing.

Spray:

Mix one can (760 mi) TAKTIC® E.C. in 50 gallons of water (equivalent to 1/2 fl. ounce per gallon of spray solution). A sprayer with a coarse nozzie delivering the solution at 70 to 150 psi is recommended. Spray the wails, floor end any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jowl, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until runoff. A second treatment is recommended to break the parasites' life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pigs (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use TAKTIC® E.C. at the same time with any other Amitraz-containing product.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. INTERVET warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET and user assumes the risk of any such use. INTERVET MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET.

© 2002 INTERVET INC.

584350B MADE IN CANADA NET CONTENTS: 760 ml (25.7 fl. oz.)

			
	Form Ap		000. Approval expires 2-28-9
SEPA Environmental Protect		Registration	OPP Identifier Number
Environmental Protect Washington, DC 2		✓ Amendment	294603
		Other	
Applicat	tion for Pesticide - Sec	tion i	
1. Company/Product Number	2. EPA Product Men	oger 3. i	Proposed Classification
54382-3	Akiva Abramovito	h [None Restricted
Company/Product (Name) Taktic Emulsifiable concentrate Miticide/Insecticide	PM# 04		
5. Name and Address of Applicant (Include ZIP Code)		eiw. In accordance wit	
Intervet Inc.	ibilii, my product i	s similar or identical in c	composition and labeling
405 State St.			
Millsborp, DE 19966			
Check If this is a new address	Product Name		
	Section - II		
✓ Amendment - Explain below.	Final printer	d labels in repsones to	
Resubmission in response to Agency letter dated	Agency lett		
		триовиоп,	
Notification - Explain below.	Other - Exp	lein below.	
Explanation: Use additional page(s) if necessary. (For sect	ion i and Saction II.)		······
The purpose of this submission is to revise the first eld statement		PR Notice 2001-1. In addition	on, the following statement is
being added to the front label: "NOTICE: This product contains harm." (per California EPA's Proposition 65 requirements).	a chemical known to the State of Ca	Ilfomia to cause birth defects	or other reproductive
main. Has canonia arno richositos co tadas atilatas).			
	Section - III		
1. Material Thie Product Will Be Packaged in:			
Child-Resistant Packaging Unit Packaging	Weter Solubie Peckaging	2. Type of Contains	<u></u>
Yes Yes	Yes	Metal	••
No No	No	Plestio	1
# "Yes" No. psf	I("Yes" No. per	Glass	
be submitted Unit Packaging wgt.		Other	(Specify)
3. Location of Net Contents Information 4. Size(a) R	Retail Container	5. Logation of Label Direct	Hone
Label Container			30718
	ograph Other		
	er glued		······································
	Section - IV	······································	
1. Contact Point		if necessery, to process the	is soplication.)
Name	Title		ne No. (include Area Code)
Mary K. Hagier	Regulatory Specialist - Pharm	1 '	
Certific	retina		6. Date Application
i cartify that the statements i have made on this form as	nd all ettachments theroto are true		Received
i acknowledge that any knowlingly false or misleading s both under applicable law.	tatement may be punishable by fil	ne or imprisonment or	(Stamped)
	3, Title		- :::::
2. Signeture	Regulatory Specialist - Phermac	suficals	
"My K. Hagle	. regulatory Schoolesset - 1. Heilinen		
4. Typad Name	5. Date		*****
Mary K. Hagler	02 May 2002)	,

Paperwork Reduction Act Notice and Instructions

Paperwork Reduction Act Notice: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460.

Instructions: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)]; 1.
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable:
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

Specific Instructions: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- Proposed Classification Specify the proposed classification of this product.
- Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only, Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- Name and Address of Applicans The name of the firm or person and address shown in your application is the person or firm to whom the resistration will be issued. If you are acting in behalf of another party, you must submit authorization from the party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- Expedited Review FIFRA section 3(e) 3(b) provides for expedited review of applications for registration, or amendments to existing registrations. that are similar, or identical to other pesticide products that are currently registered with the EPA. In order for you application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

Section II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by . . . "; "reregistration submission"; "general label revision of use directions." Attach a separate page is additional space is needed.

Section III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Backaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual ı, packets and number per retail container.
- Type of Retail Container Indicate type of container in which product will be marketed.
- Location of Net Contents Indicate the location of the net contents information for your product.
- Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 4. •• 5. Location of the Use Directions - Indicate the location of the use directions for your product.
- ••• Manner in which label is affixed to product Indicated the method product label is attached to retail container. 6.

Section-IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

i-5. Self-explanatory

6. EPA Use only



(302) 934-4340

02 May 2002

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Attn: Akiva Abramovitch
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

RE: Taktic Emulsifiable Concentrate Miticide/Insecticide EPA Reg. No. 54382-3

Dear Dr. Abramovitch,

In accordance with PR Notice 2001-1, enclosed is an amendment for the First Aid statements for the Taktic Emulsifiable Concentrate Miticide/Insecticide label (EPA Registration # 54382-3).

In addition, the following statement is being added to the front of the label as required by California EPA's Proposition 65: "NOTICE: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

A completed EPA Form 8570-1 is enclosed as well as a 5 copies of the draft label. The proposed changes to the label are highlighted in yellow on each of the 5 copies.

Thank you in advance for your attention to this matter. Please contact me by phone (302-934-4340) or e-mail (mary.hagler@intervet.com) should you have any questions.

Sincerely,

Mary K. Hagler, MS

Regulatory Specialist – Pharmaceuticals

Intervet Inc.

Enclosure

<u>Cintervet</u>

Intervet Inc.
405 State Street
P.O. Box 318
Millsboro, DE 19905-84 Rs
Tel. (102-834-8051

2



U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS 1200 Pennsylvania Ave., N.W. Washington, DC 20460-0001

EPA	Reg.	Num	be
:	5438	32-3	

Date of Issuance AIG 28 2002

NOTICE OF PESTICIDE

Registration Reregistration (under FIFRA, as amended)

Name of Pesticide Product TAKTIC EC

Term of Issuance Unconditional

Name and Address of Registrant (include ZIP Code):

Intervet Inc.

405 State Street

P.O. Box 318

Millsboro, DE 19966

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby reregistered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Registration is in no way to be construed as an endorsement or approval of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

Based on your response to the Amitraz Reregistration Eligibility Decision document, EPA has reregistered the product listed above. This action is taken under the authority of sec. 4(g)(2)(c) of FIFRA. Reregistration under this section does not eliminate the need for continued reassessment of pesticides. EPA may require submission of data any time to maintain the registration of your product.

The labeling submitted in connection with reregistration under the FIFRA is acceptable. A stamped copy of the draft label is enclosed for your records. Submit one (1) copy of your final printed labeling before you release the product for shipment. Should you have any questions, do not hesitate to contact Registration Review Manager, Dr. Akiva Abramovitch at 703-308-8328.

Signature of Approving Official:

Meredith Laws, Chief

Insecticide-Rodenticide Branch

Registration Division (7505C)

Date:

AUG 28 2002

EPA Form 8570-6

Taktic[®]

EMULSIFIABLE CONCENTRATE MITICIDE/INSECTICIDE

FOR THE CONTROL OF TICKS, MANGE MITES AND LICE ON BEEF CATTLE, DAIRY CATTLE AND SWINE

DO NOT USE ON DOGS OR HORSES (MAY CAUSE FATAL COLON IMPACTION)

AUG 28 20

Under the Federal Insecti Fundicide, and Redenticid

BPA Rog. No.

ACTIVE INGREDIENT:

Amitraz

INERT INGREDIENTS:

ACCEPTED Percent by Weight:

12.5

87.5 TOTAL 100.0

This product contains Petroleurn

EPA Reg. No. 54382-3

U.S. Patent Nos. 3,781,355 and 3,864,497

EPA Est. No. 264-CAN-001

PRECAUCION AL USUARIO: Si usted no lee inglés, no use este producto hasta que la etiqueta haya sido explicada ampliamente.

(TO THE USER: If you cannot read English, do not use this product until the label has been fully explained to you.)

KEEP OUT OF REACH OF CHILDREN

DANGER-PELIGRO

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

NOTICE: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

INTERVET INC. Millsboro, DE 19966 584300C

Product of Canada

NET CONTENTS: 760 ml (25.7 fl. oz.)

FIRST AID:

IF SWALLOWED:	Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person. Do not give anything to an unconscious person.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
IF ON SKIN:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice:
IF INHALED:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to mouth if possible. Call a poison control center or doctor for further treatment advice.
	For incidents involving HUMANS, call 1-800-228-5635, ext 132 For incidents involving ANIMALS, call 1-800-345-4735, ext 104 uct container or label with you when calling a poison control center or doctor or going for treatment

NOTE TO PHYSICIAN: Amitraz, the active ingredient in this product, is a carbamate. Do not use atropine as an antidote. Treat any overexposure symptomatically. Mucosal damage is probable which increases the risk of gastric lavage. Contains petroleum distillate — vomitting may cause aspiration pneumonia.

PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animais)

DANGER

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause altergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- · Chemical-resistant apron or coveralls over long-sleeved shirt and long pants.
- · Chemical-resistant footwear plus socks.
- · Chemical-resistant gloves.
- Chemical-resistant headgear for overhead exposure.
- Goggles or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for a washables, use detergent and hot water. Keep and wash PPE separately from other laundity.

User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Store in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

In case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER.

CHEMICAL EMERGENCY PHONE NUMBER (SPILL, LEAK, FIRE OR EXPOSURE)
1-800-424-9300

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES or DOGS - CAN CAUSE DEATHS.

DO NOT OPEN CONTAINER UNTIL READY TO USE.
USE TAKTIC®E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.

BEEF AND DAIRY CATTLE

TAKTIC® E.C. can be used on lactating dairy animals, with no withholding period for milk following application. Also, there is no post-treatment slaughter interval on beef and dairy cattle.

TICKS AND LICE:

TAKTIC® E.C. will control the following Ticks and Lice on cattle:
Lone Star Tick (Amblyomma americanum)
Guif Coast Tick (A. maculatum)
Winter Tick (Dermacentor albipictus)
Brown Dog Tick (Rhipicephalus sanguineus)
American Dog Tick (D. variabilis)
Rocky Mountain Wood Tick (D. andersoni)
Spinose Ear Tick (Otobius megnini)
Black-legged Tick (Ixodes scapularis)
Tropical Bont Tick (A. variegatum)
Cayenne Tick (A. cajennense)
Cattla Tick (Boophilus annulatus)
Southern Cattle Tick (B. microplus)

Biting Louse (Damalinia bovis)
Sucking Lice (Haematopinus eurystemus, Linognathus vituli, Solenopotes capillatus)

MITES

Scab and Mange Mites (Chorioptes bovis, Psoroptes ovis and Sarcoptes scablei var. bovis)

Spray:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. Use TAKTIC® solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Starticks, cattle ticks, sucking lice and chawing lice, particular attention should be given to the legs, axilla and groin area, udder, tail regions and head, including the ears. For Guif Coast ticks and Ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 deys later is recommended, to kill lice hatching from eggs.

Spray Dip Machine:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in t00 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scables, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments 7-10 deys apart are required to control cattle scables. Use TAKTIC® solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.

SWINE

MANGE MITE AND LOUSE (Sarcoptes scable) var. suis and Haematopinus suis): IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use TAKTIC® solutions within 6 hours of mixing.

Spray:

Mix one can (760 ml) TAKTIC® E.C. in 50 galions of water (equivalent to 1/2 fl. ounce per galion of spray solution). A sprayer with e coarse nozzle delivering the solution at 70 to 150 psi is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jowl, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until runoff. A second treatment is recommended to break the parasites' life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pigs (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use TAKTIC® E.C. at the same time with any other Amitraz-containing product.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms ere not acceptable, return at once unopened. INTERVET warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under ebnormal conditions, or under conditions not reasonably foreseeable to INTERVET and user assumes the risk of any such use. INTERVET MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET.

© 2002 INTERVET INC.

584350B MADE IN CANADA NET CONTENTS: 760 ml (25.7 fl. oz.)





STATEMENT OF PRACTICAL TREATMENT (FIRST ALD):

IF IN EYEA: HOLD EVELUS OPEN AND FLUSH WITH STEADY, CENTLE STREAM OF WATER FOR 19 MEATER GET MESCAL ATTEMPERA

IF ON SIGH: WASH WITH PLONTY OF BOLF AND WATER, GET MEDICAL ATTENTION. IF BEHALLD: RELOVE VICTIM TO FREEH MR. IF HOT SEEATHERD, GIVE ARTERIOM, RESPREADON, PREFERANCY MOUTH-TO-MOUTH GET MEDICAL ATTENTION.

PULL HERE TO OPEN PRESEN. [

IF EWALLOWED: CALL A PHYSICIAN OR POSCIAL CONTROL CENTER DO NOT HELICE VOMETRIC DEPOS PROMETLY A LURGE CLUMTITY OF HELIC EXAMINED CHAPTER OF A THESE ARE NOT AYALAKE DEMAN LARGE CHAPTERS OF WATER AVOID ALCOHOL

NOTE TO PHYBICIAN: AMTRAZ THE ACTIVE PAGREDIENT IN THIS PRODUCT, IS NOT AN ORGANICIPACIST COMPOUND, DO NOT USE ATROPINE AS AN ANTICOTE. TREAT ANY OVEREXPOSITIVE STAFFORMATICALLY, MAJOCIAL CHARGE IS PROBABLE VECO ACTIVE CANAGE. THE PRESENCE OF PETHOLIZED DISTRILATE IN THIS PRODUCT WAY POSE AN ASPIRATION PHERILADINA.

PRECAUTIONARY STATEMENTS Hazarda to Humana (and Domestic Animals)

DANGER

Corroshe. Causes interretible eye derrage. Causes stin inteston. Harmat if swallowed or absorbed through stin or ishalad. Do not get in eyes, on eith or or dothing. Audit breathing spray mist. Wear gaugles or ison sixted. Protonged or frequently repeated skin contact may cause afterpic reaction in some individuals. Wear thoroughly with scorp and vester after harding. Remove contaminated clothing and wear tooling before reuse.

Personal Protective Equipment (PPE)

- Applications and other handlers must wear:

 Chamical-resistant spron or opversite over long-sleeved shirt and long pants.
- Chemical-resistant footweer plus socks.
- Chemical-resistant gloves,
- Chemical-resistant headgest for overhead exposure.
 Googles or face shield, and chemical-resistant apron when deeping. equipment, mixing or loading.

 Do not apply this product in a way that will contact workers or other

- On not apply this product in I, way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For finestock apply or dip applications in anciosed ereast. Apply only in well-vertilizate areas. Prodow manufacturer's instructions for cleaning/maintaining PPE, if no such instructions soist for weahables, use distemperal and hot water. Keep and wash PPE applicately from other soundry.

- User Safety Recommendations

 Users should wash hands before easing, dinking, chaving gum, using schedoro, or using the tollet.
 Users should remove clothing immediately it pessible gets inside. Then
- wash thoroughly and put on dean debang.

 Users should remove PPE immediately after handling this product. Weah the cutation of gloves before temporal, a soon as possible, weeh thoroughly and change into deen ciching.

ENYROHMENTAL HAZARDS

This prediction in the instantian of aquesic invertablesias. Do not apply directly to water, or to areas where surface water is precent or to invertidal areas below the mean water mark. Do't and novel from treated areas may be hazardous to expelle organizate in adjacent sites. Do not contaminate water when disposing of equipment washwesters or master.

PHYSICAL OR CHEBROAL HAZARDS

Do not use or store rear heat or open fame:

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Store in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.



PESTICIDE DISPOSAL: Do not contaminate water, local or lead by storage or disposal. Posticide westers are toxic. Improper Copposit of excess posticide, spray neighbo or finante is a vicinion of foderst law. If shape waster cannot be disposed of by use ecconding to label instructions, contact your state posticide or Environmental Control Agency, or the Hazzantous Waste representative at the nearest EPA Regional Office for guidance. CONTAINER DISPOSAL: Triple Wate (or equivalent). Then offer to recycling or reconditioning, or purcture and dispose of in a contact familia, or by other procedures exproved by state and

In cases of appliages, cover with an absorbert such as socia and, day or sewicust. Sweep up and dispose of an directed under Storage and Oksposed.

DO NOT REUSE EMPTY CONTABLER. EMERGENCY PHONE NOS.: HQMAH — 1-800-228-8635, ast. 132 AHHAAL --- 1-000-348-4735, ext. 104 CHEMICAL (SPILLLEAK, FIRE OR EXPOSURE) 1-400-424-8330

DIRECTIONS FOR USE

if is a violation of tectoral law to use this product in a marrier inconstruct with its labeling. DO NOT USE ON HORSES of DOGS - CAN CAUSE DEATHS. DO NOT OPEN CONTARIER UNITEL READY TO USE. USE TAKTIOD EC. WITH WATER ONLT. DO NOT MIX WITH OIL OR OTHER SOLVENTS.

BEEF AND DAIRY CATTLE

TAXTICO E.C. can be used an lacturing dainy artificial, with no wayschilling period for milk following application. Also, there is no ment elementeer interval on basel and delay callie.

TICKS AND LICE:

TAKTION E.C. will constal the following Ticks and Lice on cases: Lone Star Tick (Amblyomma emericanum) Guil Coast Tick (A. meadeann) Water Tick (Demincentor abjectus) Brown Dog Tick (Phiplosphaka sanguineus) American Dog Tick (D. variabille) Rocky Mountain Wood Tick (D. andarson) Spincer Est Tick (Chitain magniti) Stack lagged Tick (hocker scapularis) Tropical Bont Tick (A variegation) Cayerna Tick (A. cajarnansa) Cattle Tick (Booptine arrulate) Southern Cettle Tick (B. micropater) Ritario i custo (Chartalinia hossia) Sucking Lice (Heemelopinus suryetomus, Linopratius vitali,

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Sciencecies espiliatus)

Scale and Marca Miles (Chorlepius boris, Psoroptus oris and Securitat populai var. boris)

Sorwy:

spray: For control of Sides and Side, mist one can (760 ml) of TAKTICOS E.C. in 190 gallons of water, for control of misse, mix one can of TAKTICOS E.C. in 50 gallons of water. Uses TAKTICOS exclutions within 8 hours of mixing. Uses up to 2 gallons of spray for a busy grown artisted. It is important to well the artisted thoroughly and that The extray personates to the pian until number. For Lone Star toke, called soile, sucking time and chewing time, personal extension

should be given to the large souls and grain area, uniter, tall regions and head, including the ears. For Gull Costel Sides and Ear Sides, treat the house, same, shoulder area and neck with a low pressure apray. For control of tice, a second treatment 10-14 days later is recommended, to its first heatering from eggs.

Sprey Oto Machine:

For constant of Balta and Balt, mile care case (760 mg of TAKTICO) E.C. In 100 gallorie of weiser, for control of miles, mile one can all TAKTICOS E.C. in 50 paisons of water. To control castle acception, spokestions at could be made as instructed by USDA, APHIS, VS building. Two treatments 7-10 days apart are required to control castle acables. Use TAXTICO solutions within 6 hours of mixing. Use up to 2 gallons of soray for a half grown animal. It is important to want the animal. Executed by and that the aposty paralleles to the side until number.

SWINE

MARGE MITE AND LOUSE (Serroptes scaled yes, such and licometopina mist

SAPORTANT

Plantons lead from pan and cover chrising bowls. Framove and destroy bedding. Hose out faces and excess tood. Use TAKTHOS solutions within 6 hours of midding.

Spray,

HEX one can (700 ml) TAXTION E.C. In 50 gallons of water control of the control per patient of spray existence of water (equivalent to 1/2 it control per patient of spray existence). A persper with a course notice delivering the solution at 70 to 160 per la recommended. Spray the water, foor and any littings in the part. Spray of arrivals (at the same time) whether visibly allocated or not. Spray the arrivals until the midster runs off, paying parasular attaction to treat the lovel, logs, hadde the ears and undertaked of the local. It is invested that the construction of the same and undertaked of the local. It is invested that the construction of the same part undertaked of the local. It is invested that the construction of the same are small undertaked on the local below the same and the same same and undertaked on the local below the same and the same are small undertaked on the local below the same and the same are small undertaked on the local below the same are small undertaked that the local same and the same are small undertaked the local same are small undertaked that local same are small undertaked that the local same are small undertaked that local same are small undertaked body. It is important that the spray parastrates to the sids unst natical. A second treatment is recommended to break the parastrant sta cycles. Make the application 7-10 days after the first treatment for mile control, and 10-14 days for tice control.

An element to except promp plays (plainterecenses) is to do man in a suitable-eized container. Dip 30 enimels and then replace do wash. Use dip week to treat premises.

Do not treat enimels more than 4 times per year.

Do not apply to swine within three days of sizuantez.

Do not use TAXIXXD E.C. at the same time with any other Ambra. containing product.

HAPORTAINT MOTICE DISCLAIMER

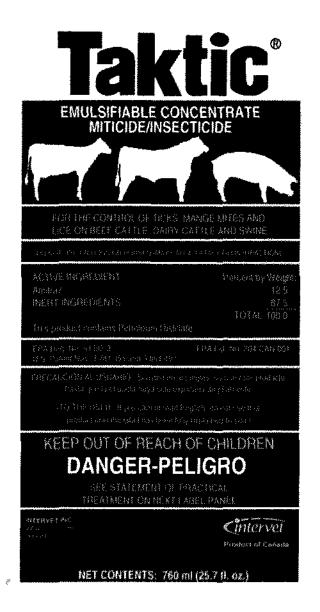
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product conforms to the standard description on the label and is reasonably to be
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INTERVET MARCES IND OTHER WARMANTY, EXPRESSED OR SAFLED,
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concentration, special, indeed or instituted demograte resulting from the use or
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of RETERVET.

S 2000 INTERVET SKC.

MADE SHOUNDA NET CONTENTS: 700 HE (PA.) S. (CL.)



Current Product Label





PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wasters are toxic. Improper disposal of excess posticide, sprey mixture or itneste is a violation of faderal law. If these wastes cannot be disposed of by use according to least instructions, contact your state pasticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. CONTAINER DISPOSAL: Triple tinse (or equivalent). Then offer tor recycling or reconditioning, or puncture and dispose of in a standary landfill, or by other procedures approved by state and local authorities.

in case of spilege, cover with an absorbent such as socia seh. clay or earedust. Sweep up and dispose of as directed under Storage and Disposal

DO NOT REUSE EMPTY CONTAINER.

EMERGENCT PHONE NOS.:

HUMAN - 1-800-228-6835, ext. 132

Ambhal --- 1-800-345-4735, ext. 104 Chemical (Sprli, Leak, Fire or exposure) 1-600-424-8300

DIRECTIONS FOR USE

It is a violation of federal law to case this product in a manner incorrelation with its labeling.

DO NOT USE ON HORSES or DOGS - CAN CAUSE DEATHS. DO NOT OPEN CONTAINER UNTIL READT TO USE. USE TAXTICS E.C. WITH WATER ORLY. DO NOT MIX WITH or on dther solvents.

BEEF AND DAIRY CATTLE

TAKTICS E.C. can be used on factating daily animals, with no withholding period for milk following application. Also, there is no post-treatment staughter interval on beef and dainy cates.

TICKS AND LICE:

TAKTIOS E.C. will conside the following This and Lice on callie: Lone Star Tick (Amblycomme emericanum) Gulf Coses Tick (A. maculasum) Winter Tick (Dermacentur albipiotus) Brown Dog Tick (Phipiosphalus songuineus) American Cog Tick (D. variabilis) Rocky Mountain Wood Tick (D. endersonl) Spinosa Est Tick (Osobus megnini) Black-lagged Tick (Irodes scepularis) Tropical Bont Tick (A. variegatum) Cayerne Tick (A. csiennense) Cattle Tick (Scoophilus ennudenus) Southam Cattle Tick (8. mkropks) Biting Louse (Damakila boxis) Sucking Lice (Heemstopinus eurystemus, Linognestius vital), Solanopolea capitatus)

Scap and Manga Mittes (Chorisptes bovis, Peoroptes ovis and Sercoptes scablel ver. bovis) бриту:

For control of ticks and fice, mix one can (160 mi) of TAKTICO E.C. in 100 gations of water, for control of miles, mix one can of TAKTICS E.C. in 50 gallons of water. Use TAKTICS adultions within 6 hours of mixing. Use up to 2 gasons of spray for a buly grown areinal. It is important to well the areinal thoroughly and that the spray penetrates to the skin until non-off. For Lone Star ticks, callie ticks, sucking lice and chawing lice, persoular attention

should be given to the legs, exilia and groin area, udder, tail regions and head, including the care. For Gulf Coast fictis and Ear ficis, treat the head, ears, shoulder area and neck with a low pressure sprey. For control of Soa, a second treatment 10-14 days later is recommended, to this lice heliciting from opps.

Sprey Olp Machine:

For control of ficks and lice, mix one can (760 ml) of TAKTIOD E.C. in 100 gallione of wester, for control of militas, mix one can of TAKTICO E.C. in 50 gazons of water. To control casile stables, applications should be made as instructed by USOA, APAIS, VS bulletins. Two reciments 7-10 days open are required to control castle scatists. Use TAKTICO solutions within 6 hours of mixing. Use up to 2 galors of spray for a first grown ariend. It is important to wat the animal thoroughly and that the spray penetralise to the akin und nun-off.

SWINE

MANGE MITE AND LOUSE (Sarcoptes ecable) var. aufa and Hammatonings suist:

IMPORTANT

Remove lead from pen and cover drinking boxle. Remove and destroy hedding. Tiose out facts and excess feed. Use TAKTIC® solutions within 6 hours of misting.

Spray:

this one can (760 ms) TAKTIOD E.C. in 50 gallons of water (equivalent to 1/2 ft. curice per gation of spray solution). A sprayer with a coerse nozzie delivering the solution at 70 to 150 psi is recommended. Spray the wells, floor and any Ribngs in the pen-Spray of enimetal (at the same time) whether visibly effected or not. Spray the enimetals until the mixture runs off, paying persicular attention to meet the joint, logs, Inside the ears and underside of the body. It is important that the apray penetrates to the aids until run-oit. A second treatment is recommended to break the parasites' the cycles. Make the application 7-10 days after the first treatment for male control, and 10-14 days for see control.

An elemente to epreying young pige (pigiete/weanere) to 60 them in a suitable-stred container. Dip 30 enimels and then replace dip west. Use do wash to treat premises.

Do not treat animals more than 4 times per year

Do not apply to earing within three days of elaughter.

Do not use TAKTIOS E.C. at the same time with any other Americacontaining product.

HAPORTANT HOTICE: BIRCLASHER

IMPTOR I AND I HOLD MAD AND ADMINISTRATION OF USING, If some and most acceptable, where at once arrappend. INTERPVET was not once that the product conforms to the channels description on the label and is researched at Lor product conforms to the channels described in the basis and is researcishly to be an purpose stated on the basis used in accordance with the described conformation of the purpose stated on the basis when used in accordance to the the accordance of the product community to label institutions or under alternative and confidence, of under confidence and researcish to institutions are understanded to the product constanded to the product of the product and the product of
O 2000 INTERVIET INC.

MADE IN CANADA HET CONTENTS: 750 mi (35.FR. oc.)





September 12, 2001

Akiva Abramovitch, Ph.D., Chemist Insecticide-Rodenticide Branch Registration Division (7505C) USEPA Headquarters Ariel Rios Building 1200 Pennsylvania Ave. N.W. Washington, DC 20460

RE: Taktic®EC (amitraz); EPA Reg. No. 54382-3

Dear Dr. Abramovitch,

As requested in your phone message today, please find enclosed a current product label and a paper copy of the current product label for Taktic[®] EC. Also enclosed is a copy of the EPA stamped label (27 April 1999) that was faxed to you 07 September 2001.

Updated labels regarding PR Notice 2001-1 (First Aid Statements on Pesticide Product Labels) will be submitted at a later date.

If you have any further questions, please contact me by e-mail (<u>lee.whaley@intervet.com</u>) or by phone at (302) 934-4385.

Sincerely,

S. Lee Whaley, MS

Manager, Regulatory Affairs-Pharmaceuticals

Intervet Inc.

Enclosures





intervet inc. 405 State Street P.O. Box 318 Millsboro, DE 19966 0318 Tel. (302) 934-8051 FAX (302) 934-4292

Label C - Proposed Label January 11, 1999, 4 pages

ACCEPTEL

APR 2 7 1999

Under the Pederal Insections, Pungistin and Roderpleide Act, as amended, for the punishe Polistered under BPA Reg. No. 54 542



his product contains Petroleum Distillate.

Taktic®

EMULSIFIADLE CONCENTRATE MITICIDE/INSECTICIDE



FOR THE CONTROL OF TICKS, MANGE MITES AND LICE ON BEEF CATTLE, DAIRY CATTLE AND SWINE

DO NOTUSE ON DOGS OF HORSES (MAY CAUSE FATAL COLOR/ IMPACAS"

ACTIVE INGREDIENT:

Amitraz

INERT INGREDIENTS

Percent by Weight

125

0.001 JATOT

The cradial narray last variation to

EPA Rea No. 54382-3

NO. 5438Z-3

EPA Est No. 045639-040-001

U.S. Palent Nos. 3 781,355 and 3,864,497

PRECAUCION At, USUARIO Si usted no lee inglés, no use este producio hasta que la etiqueta haya sido explicado ampliamente.

(TO THE USER. If you cannot read English, do not use this product until the label has been fully explained to you.)

KEEP OUT OF REACH OF CHILDREN

DANGER-PELIGRO

SEE STATEMENT OF PRACTICAL TREATMENT ON BACK LABEL

Hoechal Raussel Vel

reconstruction of the control of the

VET CONTENTS: 760 ml (25.7 fl. oz.

Page 1 of 4 January 11, 1999 💤 Hoechst 🖥

STATEMENT OF PRACTICAL TREATMENT (FIRST AID):



CONTROJ CENTER IN LEDIATELY. IT IS PREFERBLE TO USE QUITTRIC LAVAG LINDER MEDICAL SIZE SERVISION DATE TO APPRATION HAZARD. TO NOT REDUCE POMPING OR GIVE ANYTHING BY MOUTH TO AN UNDONSCIONE PERSON. MEDICAZ IS NOTION ORGANIZOPHOSPHURIUS COMPOUND, DONOT USEATROPINE A MEDICAZ IS NOTION ORGANIZOPHOSPHURIUS COMPOUND, DONOT USEATROPINE A MEDICATIONTE.

F IN EYES FLUSH WITH PLENT OF WATER, GET MEDICAL ATTENTION

FON SUN: WASHINGTON

PRECAUTIONARY STATEMENTS Hazards to Humans (and Domestic Animals)

DANGER



psorbeckhroughtskin. Refeated slin contactinay cause an allegic reack

Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

Chemical-resistant apron over long-sleeved shirt and long pants. Chemical-resistant foetweer plus socks.

Chemical-resistant gloves.

Chemical-resistant headgear for overhead exposure.

Goggles or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- Users should wash hands before eating, drawing chewing gum, using tobacco, or using the tollet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product.
 Wash the outside of gloves before removing. As soon as possible, wash theroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This posticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to aquatic greatisms in adjacent sites. Do not contaminate water when deposing of equippingit washwaters or insate.

PHYSIONLOR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

. STORAGE AND DISPOSAL

STORAGE Not for storage in and around the home environment. Suore in ofiginal container in a lockett dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

Page 2 of 4 January 11, 1999 IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN:

Amitraz, the active ingredient in this product, is not an organophosphorus compound. Do not use atropine as an antidote. Treat any overexposure symptomatically. Mucosal damage is probable which increases the risk of gastric lavage. The presence of petroleum distillate in this product may pose an aspiration pneumonia hazard.

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged on frequently repeated skin contact may cause allergic reaction in some cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove containing the lothing and wash clothing before relief.



Page 3 of 4 January 11, 1999

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state posticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

in case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER. **EMERGENCY PHONE NOS.:** HUMAN, FIRE, SPILLS, ENVIRONMENTAL:

1-800-228-5635, Ext. 132 ANIMALS: 1-800-345-4735, Ext. 104

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES of DOGS - CAN CAUSE DEATHS. DO NOT OPEN CONTAINER UNTIL READY TO USE. USE TAKTICS E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.

BEEF AND DAIRY CATTLE

TAKTIC® E.C. can be used on factating dairy animals, with no withholding period for milk following application. Also, there is no post-treatment slauchter interval on beef and dairy caltie.

TICKS AND LICE:

TAKTIC® E.C. will control the following Ticks and Lice on cattle: Lone Star Tick (Amblyomma americanum) Gulf Coast Tick (A. maculatum) Winter Tick (Dermacentor albipictus) Brown Dog Tick (Rhipicephelus sanguineus) American Dog Tick (D. variabilis) Rocky Mountain Wood Tick (Dermacentor andersoni) Spinose Ear Tick (Otobius megnini) Black-legged Tick (Ixodes scapularis) Tropical Bont Tick (A. variegatum) Cayenne Tick (A. cajennense) Cattle Tick (Boophilus annulatus) Southern Cattle Tick (B. micropius) Biting Louse (Damaiinia bovis) Sucking Lice (Haematopinus eurystemus, Linognathus vituli,

Scienopoles capillatus)

Scab and Mange Mites (Chorioptes bovis, Psoroptes ovis and Sarcoptes scabiei var. bovis)

For control of ticks and lice, mix one can (760 ml) of TAKTIQ® E.C. in 100 gallons of water; for control of mites, mix one cab of TAKTICO E.C. in 50 gallons of water. Use Taktico solutions : within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Star ticks, cattle ticks, sucking lice and chewing lice, particular attention

should be given to the legs, avoils and groin area, udder, tail regions and head, including the ears. For Gulf Coast ticks and ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice hatching from egos.

Spray Dip Machine:

For control of ticks and lice, mix one can (760 mil) of TAKTIO® E.C. in 100 gallions of water, for control of mites, mix one can of TAKTICE E.C. in 50 gallons of water. To control cattle scables, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments 7-10 days apart are required to control cattle scattles. Use Taktica solutions within 8 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.

SWINE

MANGE MITE AND LOUSE (Sarcoptes scable) var. suis and Haematooinus suis):

IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use TAKTICS sciutions within 6 hours of mixing.

Mix one can (760 ml) TAKTIC® E.C. in 50 gallons of water (equivalent to 1/2 ft. ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 pel is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the modure runs off, paying particular attention to treat the jowl, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until runoff. A second treatment is recommended to break the parasites' life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pigs (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use Taktic® E.C. at the came time with any other amitraz containing product.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using, if terms are not acceptable, return at once unopened. HOECHST ROUSSEL VET werrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions. or under conditions not reasonably loreseeable to HOECHST ROUSSEL VET. ard user assumed his risk of any such use. HOECHST HOUSSEL VET WAKES NO "THER WARRANTY, EXPRESSED OR IMPLIED, INCLUCING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall HOECHST ROUSSEL VET be lable for consequential, special, indirect or incidental damages resulting from the use or handing of tigs groduct. The loregoing conditions of sale and warranty can be varied-only by amagneoment in ending signed by a duly authorized regree-vazive of-IOECHST_FOUSSELDED.

Taktic (amitraz) is a registered trademark of Hoechst Roussel Vet GmbH.

The name and logo HOECHST are registered trademarks of HOECHST AG.

584350-5/98 MADE IN CANADA NET CONTENTS: 780 m.l (23.7 ft. 62.)

Page 4 of 4 January 11, 1999 Telefax Transmittal
Cover sheet



Intervet Inc. 405 State Street P.O. Box 318 Millsboro, DE 19966 (302) 934-8051

September 7, 2001

pages including cover sheet.

PERSON TO:	COMPANY/DEPT TO:	FAX NUMBER:
Dr. Akiva Abramovitch	Environmental Protection Agency Insecticide-Rodenticide Branch Registration Division (7505C)	703-305-6596

PERSON FROM:	COMPANY/DEPT FROM:	FAX NUMBER:
		<u>L</u>

S, Lee Whaley, MS Manager, Regulatory Affairs – Pharmaceuticals

Intervet Inc. Milisboro, Delaware Fax: 302-934-4209 Phone: 302-934-4385

RE: Taktic EC (Amitraz); EPA Registration No. 54382-3

Dear Dr. Abramovitch,

This fax follows our conversation this morning regarding the above-mentioned product and provides you a copy of the 27 April 1999 letter from Mr. Leonard Cole (EPA). The 27 April 1999 letter includes a copy of the EPA-stamped tabel incorporating the changes required by the amitraz re-registration eligibility decision (RED). Please feel free to contact me by phone (302-934-4385) or e-mail (lee,whaley@intervet.com) if I can be of further assistance.

Sincerely.

S. Lee Whaley, MS

(Manager, Regulatory Affairs - Pharmaceuticals; Intervet Inc.)

Whaley

Intervel

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED, AND MAY CONTAIN PROPRIETARY INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND EXEMPT FROM DISCLOSURE UNDER APPLICABLE LAW. IF YOU ARE NOT THE ADDRESSEE, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION, OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, NOTIFY US IMMEDIATELY BY TELEPHONE (COLLECT). THANK YOU.

reid 4/28/99



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

APR 27 1999

John L. Lauber, Ph.D. Hoechst Roussel Vet 30 Independence Blvd. P.O. Box 4915 Warren, New Jersey 07059-0915

Dear Dr. Lauber:

Subject: Labeling Amendment

Taktic EC

EPA Registration No. 54382-3

Your submission dated 31 March 1999

The labeling amendment referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, has been received and reviewed, and the labeling is acceptable. Please submit three (3) copies of your final printed labeling incorporating the changes prior to releasing your product for shipment. A stamped copy is enclosed for your records.

Sincerely,

Leonard Cole

Insecticide-Rodenticide Branch Registration Division (7505C)

Enclosure

Label C - Proposed Label January 11, 1999, 4 pages

ACCEPTEL

APR 2 7 1989

Roberton Industrial

April 2 7 1989



This product contains Petroleum Distillate.

EMULSIFIABLE CONCENTRATE MITICIDE/INSECTICIDE KEEP OUT OF REACH OF CHILDREY **DANGER-PELIGRO** : Hoechst

NET CONTENTS: 760 inl (25.7 fl. 6z.)

STATEMENT OF PRACTICAL TREATMENT (PIRST AID):



CONTRO CENTER MECHATRY. IT IS HISTERIAL BOUNE QUETTE: LANGE MORPH EXCAL BY ENVIRONDUE TO JAP RATION (42ARD. JO NOT NAUCO CHEMIC OR OR ANYTHING BY MOLTET TO AN UNCONSCIOUS PERSON MEMOZ IS NOTHIN CHICAUS PHOSPHUMUS CONTOURD. DONOT USES TROBUS MEMOZ IS NOTHIN CHICAUS PHOSPHUMUS CONTOURD. DONOT USES TROBUS

FIN EYES PLUSH WITH PLENT OF WATER, GET MENCAL AT ISHTO

PRECAUTIONARY STATEMENTS Hazards to Humans (and Domestic Animals)

DANGER



Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before name.

Personal Protective Equipment (PPE)

Applicators and other handlers must year:

Chemical-resistant apron over long-sleeved shirt and long perms. Chemical-resistant foctoring plus socies.

Chemical-resistant gloves.

Chemical-resistant headgest for overhead exposure.

Goggles or face shield, and chemical-resistant aprox when cleaning equipment, mixing or loading.

Do not apply this product in a way that will contact workers or other persons, either directly or through difft. Only protected hundlers may be in the area during application.

For fivestock spray or dip applications in enclosed areas: Apply only to well-ventilated areas.

Follow manufacturer's instructions for cleaning/mainteining PPE. If no such instructions add for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- Users should wash hands before eating, drawing, cheeling girss, uting totacco, or using the tollet.
- Users should remove clothing immediately if pesticide gets isside. Then weath thoroughly and put on clean distring.
- Users should remove PPE introductory after handling this product.
 Wash the cutside of gloves before removing. As soon as possible, wash thoroughly and change into clean cluthing.

ENVIRONMENTAL HAZARDS

This posticide is load: to fish and aquatic invertebrates. Do not apply directly in water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate water when disposing of equipment washwaters or rinsale.

PHYSICAL OR CHEMICAL HAZARDS
On not use or story mear heat or open flame.

STORAGE AND DISPOSAL

STOFLAGE: Not for storage in and around the home environment. Some in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from treating.

> Page 2 of 4 January 11, 1999

IF IN EYES: Hold syclids open and finsh with steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF SWALLOWED: Cail a physician or Polson Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN:
Amitraz, the active ingredient in this product, is not an organophosphorus compound. Do not use atropine as an antidote. Treat any overexposure symptomatically. Mucosal damage is probable which increases the risk of gastric lavage. The presence of petroleum distillate in this product

may pose an aspiration pneumonia

bazard.

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

PESTICIDE DISPOSAL: Do not conteminate water, food or feed by storage or disposal. Posticide wastes are toxic. Improper disposal of excess positicide, apray mixture or rineste is a violation of federal law. If these wastes cannot be dispused of by use according to label instructions, contact your state pastición or Environmental Control Agency, or the Huzardous Wests representative at the nearest EPA Regional Office for guidance. CONTAINER DISPOSAL: Triple rivine (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary lendfill, or by other procedures approved by state and local authorities.

in case of apiliage, cover with an absorbent such as socia ash. cley or sewdust. Sweep up and dispose of at directed under Storage and Discount.

DO NOT REUSE EMPTY CONTAINER.

EMERGENCY PHONE NOS.:

Human, Prie, Spills, Environmental: 1-800-229-5635, Ext. 1:2

ANMALS: 1-800-345-4735, Ext. 104

DIRECTIONS FOR USE

it is a violation of federal law to use this product in a manner incorrelatent with its labeling.

DO NOT USE ON HORSES or DOGS - CAN CAUSE DEATHS.

DO NOT OPEN CONTAINER UNTIL READY TO USE.

USE TAKTICO E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.

BEEF AND DAIRY CATTLE

TAKTION E.C. can be used on lackeling daily animals, with no withholding period for milk following application. Also, there is no post-treatment signification interval on beef and dairy castle.

TICKS AND LICE:

TAKTION E.C. will control the following Ticks and Lice on cattle:

Lone Star Tick (Ambiyomma americanum)

Gulf Coast Tick (A. maculatum)

Winter Tick (Demacentor abjoictus)

Brown Dog Tick (Rhipicephalus senguineus)

American Dog Tick (D. variabilis)

Recisy Mountain Wood Tick (Dermacersor anderson)

Spinose Ear Tick (Olobket megnini)

Stack-legged Tick (handes ecocularis)

Trapical Bont Tick (A. variegetum)

Cayenne Tick (A. cajennense)

Cattle Tick (Boochius armaintus)

Southern Cattle Tick (B. microphus)

Biting Louise (Damalinie bovis)

Sucking Lice (Haematopinus aurystemus, Linograthus vituli,

Solenopotes capilletus)

Scalo and Mange Mittes (Choriopise bovis, Psoropias ovis and Sarcoptee scribini var. bovis)

Spray:

For control of ticks and flow, mix one can (750 mit of TAKTION) E.C. in 100 gallions of water; for control of miles, mix one can of TAKTICS E.C. in 50 gallons of water. Use Yaldics solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-oil. For Lone Star ticks, cattle ticks, sucking lice and chewing lice, particular attention should be given to the legs, sxills and grain area, udder, tail regions and head, including the sers. For Gulf Coast ticks and ear ticks. treat the head, ears, shoulder area and neck with a low pressure sorey. For control of fice, a second treatment 10-14 days later is recommended, to kill like hatching from ugos.

Spray Dip Machine:

For control of ticks and lice, mix one can (780 mg of TAKTIOS E.C. in 100 gallons of water; for control of miles, mix one can of TAKTICS E.C. in 50 guillone of water. To control cattle scables, applications should be made as instructed by USDA, APHIS, VS building. Two restructe 7-10 days apart are required to control calls acables. Use Taktion schallone within 8 hours of mixing. Use up to 2 gallone of spray for a fully grown enimei. It is important to not the animal thoroughly and their the apray penetrates to the side until nat-oil.

SWINE

MANGE MITE AND LOUSE (Sercepter scable) ver. suit und Hammadogalnum mukili;

BURCHTANT

Remove feed from pen and cover drinking bowls. Flamove and destroy badding. Hose out faces and excess feed. Line TAKTICS solutions within I hours of mixing.

Sprey:

Mits one can (760 m2) TAKTIOS E.C. in 50 gallons of water (equivalent to 1/2 ft, ounce per gallon of apray solution). A aprayer with a coarse nozzle delivering the solution at 70 to 160 pel is recommended. Spray the walls, floor and any fittings in the pen. Spray of animals (at the same time) whether visibly affected or not. Spray the acomais until the mixture runs off, paying particular attention to knot the jowl, legs, inside the sers and underside of the body. It is important that the agrey penetrates to the skin unif runoff. A second treatment is recommended to break the persisted life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pige (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treet premises.

Oo not treat aritmaki more than 4 times per yeer.

On not apply to entire within these days of staughter.

Do not use Taktion E.C. at the prime time with any other amiraz containing product.

SMORTANT NOTICE: DESCLASHED

Florid "MPORTANT NUTTUR: DRICLARMEN" before buying or using, if testan new table, relian at arce incomed. HORCHST ROUSSEL VET warrants arriy that the product contains to the electrical description up the latest and is sorebly it for the purpose stated on the label when used in accordance with discripts under noiseal obtailions of use. This werenity does not extend to the use of this president continues to label feetpeplicus or under abre or under conditions not reasonably igneemble to HOECHET ROUSEEL VET, and user assumes the risk of any such use. HOSCHIET ROUGHEL VET LANCES NO OTHER WARRANTY, EXPRESSED OR MPLIED, MOLLCHIE ANY BAPLED WARRANTY OF PITHESS FOR A PARTICULAR PURPOSE OR OF MERCHANTAGELITY. In the case shall HOECHIST ROUSSEL VET be fable for communitation, special, indicate or indicated damages mention from the use or humbing of this product. The foregoing conditions of sale and substantly can be abused only by an agreement in unling signed by a daily authorized representative of HOECHST ROUSSEL VET.

Tablic (amitrat) in a registered trademark of Hospitel Roussel Vet Godd-L The name and logo HOBCHET are registered trademarks of HOECHET AG.

CTIONS HTT VIEW SEASON-SING MADE IN CANADA MET CONTENTS: TOO CALCULT S. OC.)

Telefax Transmittal
Cover sheet



Intervet Inc. 405 State Street P.O. Box 318 Millsboro, DE 19966 (302) 934-8051

September 7, 2001

6...pages including cover sheet.

PERSON TO:	COMPANY/DEPT TO:	FAX NUMBER:
Dr. Akiva Abramovitch	Environmental Protection Agency Insecticide-Rodenticide Branch Registration Division (7505C)	703-305-659 6

PERSON FROM: COMPANY/DEPT FROM: FAX NUMBER:

S. Lee Whaley, MS
Manager, Regulatory Affairs Pharmaceuticals

intervet Inc. Milisboro, Delaware Fax: 302-934-4209 Phone: 302-934-4385

RE: Taktic EC (Amitraz); EPA Registration No. 54382-3

Dear Dr. Abramovitch,

This fax follows our conversation this morning regarding the above-mentioned product and provides you a copy of the 27 April 1999 letter from Mr. Leonard Cole (EPA). The 27 April 1999 letter includes a copy of the EPA-stamped label incorporating the changes required by the amitraz re-registration eligibility decision (RED). Please feel free to contact me by phone (302-934-4385) or e-mail (lee.whaley@intervet.com) if I can be of further assistance.

Sincerely,

S. Lee Whaley, MS

(Manager, Regulatory Affairs - Pharmaceuticals; Intervet Inc.)

& Whaley

(Intervel)

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED, AND MAY CONTAIN PROPRIETARY INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND EXEMPT FROM DISCLOSURE UNDER APPLICABLE LAW. IF YOU ARE NOT THE ADDRESSEE, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION, OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, NOTIFY US IMMEDIATELY BY TELEPHONE (COLLECT). THANK YOU.

reid 4/28/99



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

APR 27 1999

John L. Lauber, Ph.D. Hoechst Roussel Vet 30 Independence Blvd. P.O. Box 4915 Warren, New Jersey 07059-0915

Dear Dr. Lauber:

Subject: Labeling Amendment

Taktic EC

EPA Registration No. 54382-3

Your submission dated 31 March 1999

The labeling amendment referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, has been received and reviewed, and the labeling is acceptable. Please submit three (3) copies of your final printed labeling incorporating the changes prior to releasing your product for shipment. A stamped copy is enclosed for your records.

Sincerely,

Leonard Cole

Insecticide-Rodenticide Branch Registration Division (7505C)

Enclosure

Label C - Proposed Label January 11, 1999, 4 pages

ACCEPTEL

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This product contains Petroleum Distillate.

Taktic

EMULSIFIABLE CONCENTRATE MITICIDE/INSECTICIDE



FOR THE CONTROL OF TICKS MANGE MITTER AND LICE'ON BEEF CATTLE, DAIRY CATTLE AND SMINE

TO STALE DESERTA COGGIORINGASES MONOCALSENIAR LOCUDE TO ANALLY

ACTIVE INGREDIENT:

Am:lraz

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SP4 Req No 54382-3

SFA Estinoveninoveno:

U.S. Palem Nos. 3 731 355 333 361 45

PRECAUCION AL USUARIO - S. usted on tell-logies indicate esta product.

Vasta due in enquetamble social gascato tensi lancote.

(TO THE USER) if you cannot read Emptish, do not use this product until the Pibs, has been faily explained by job it.

KEEP OUT OF REACH OF CHILDREN

DANGER-PELIGRO

SEE STATEMENT OF PRACTICAL TREATMENT ON BACK LABEL

Hoechst Bausset Vet

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NET CONTENTS: 760 ml (25.711. 62.)

Page 1 of 4 January 11, 1999

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STATEMENT OF PRACTICAL TREATMENT (PIRST AID):



CONTROCENTER RECORTES. IT IS PRESENTED USE CANTRIC LAVADA INDEPARED AND STRUCTURE TO ASSENTATION AND STRUCTURE TO ASSENTATION AND STRUCTURE FOR STRUCTURE OF ANY THE WAY MOUTH TO ASSENTATION OF FOR STRUCTURE FOR S

FIN EYES PLUSH WITH PLENTY OF WATER, GET MENCAL AT ENTIRE

OH SAN: WASHING

PRECAUTIONARY STATEMENTS Hazards to Humans (and Domestic Animals)

DANGER



osorber arrough fixin. Reflected sign contact may coule an allegic responsers individual

Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear.

Chemical-resistant apron over long-slowed shirt and long parts. Chemical-resistant foctorear plus socks.

Chemical-resistant gloves.

Chemical-resistant headgear for overhead exposure.

Goggles or lace shield, and chemical-resistent apron when cleaning equipment, mixing or loading.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

Follow manufacturer's instructions for cleaning/maintaining PPE. It no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- Users should wash hands before eating, drinning, chewing gum, using tobacco, or using the tollet.
- Users should remove clothing immediately if posticide gets inside. Then
 wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product.
 Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is known to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intentidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent sites. Do not contaminate water when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS
Do not use or store near heat or open fame.

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Sions in original container in a locked dry piace. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

Page 2 of 4 January 11, 1999 IF IN EYES: Hold cyclids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN:

Amitraz, the active ingredient in this product, is not an organophosphorus compound. Do not use atropine as an antidote. Treat any overexposure symptomatically. Mucosal damage is probable which increases the risk of gastric lavage. The presence of petroleum distillate in this product may pose an aspiration pneumonia hazard

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.





PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pasticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pasticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

In case of spilings, cover with an absorbent such as social ash, clay or sewdust. Sweep up and dispose of as directed under Storage and Disposal.

do not reuse empty container.

EMERGENCY PHONE NOS.:

HUMAN, FIRE, SPILLS, ENVIRONMENTAL:

1-800-228-5635, Ext. 132

ANIMALS: 1-800-345-4735, Ext. 104

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES OF DOGS - CAN CAUSE DEATHS.
DO NOT OPEN CONTAINER UNTIL READY TO USE.
USE TAKTICO E.C. WITH WATER ONLY. DO NOT MIX WITH
OIL OR OTHER SOLVENTS.

BEEF AND DAIRY CATTLE

TAKTICS E.C. can be used on lactating delay animals, with no withholding period for milk following application. Also, there is no post-treatment slaughter interval on beel and dairy cattle.

TICKS AND LICE:

TAKTION E.C. will control the following Ticks and Lice on cattle: Lone Star Tick (Amblyonima americanum)

Gulf Coast Tick (A. maculatum)

Winter Tick (Demnacentor albipictus)

Brown Dog Tick (Phipicephalus sanguineus)

American Dog Tick (D. variabilis)

Rocky Mountain Wood Tick (Dermacenics andersoni)

Spinose Ear Tick (Otobius megnini)

Black-legged Tick (brodes scapularis)

Tropical Bont Tick (A. verlegatum)

Cayenne Tick (A. calennense)

Cattle Tick (Boophilus annulatus)

Southern Cattle Tick (B. micropius)

Biting Louse (Damalinia bovis)

Sucking Lice (Haematopinus eurystemus, Linognathus vituli. Solenopotes capillatus)

LITES

Scab and Mange Mittes (Chorioptes bovis, Psoroptes ovis and Sarcoptes scabiel var. bovis)

Sorsv:

spray:
For control of ticks and lice, mix one can (760 ml) of TAKTIC®
E.C. in 100 gaillons of water, for control of mites, mix one can of
TAKTIC® E.C. in 50 gallions of water. Use Taktic® solutions
within 8 hours of mixing. Use up to 2 gallions of spray for a fully
grown animal. It is important to wet the animal thoroughly and that
the spray penetrates to the skin until run-off. For Lone Star ticks,
cattle ticks, sucking lice and chewing lice, particular attention

should be given to the legs, axilia and groin area, udder, tail regions and head, including the ears. For Gulf Coast ticks and ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of sice, a second treatment 10-14 days later is recommended, to kill like hatching from eggs.

Spray Olg Machine:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scables, applications should be made as instructed by USDA, APHIS, VS builletins. Two treatments 7-10 days apart are required to control cattle scables. Use Taktic® solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.

SWINE

MANGE MITE AND LOUSE (Sarcoptes scabiel ver. suis and Hisematopinus suis):

IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use TAKTICS solutions within 6 hours of mixing.

Spray:

Mix one can (760 ml) TAKTICS E.G. in 50 gailons of water (equivalent to 1/2 ft. ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 psi is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the joint, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until runoff. A second treatment is recommended to break the parasites! life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pige (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

On not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use Taktic® E.C. at the take time with any other amitrazionstaining product.

IMPORTANT NOTICE: DISCLAIMER

Rense TMPORTANT NOTICE: DISCLAMEER' before buying or using, if terms are not acceptable, return at once unopered. HOECHST ROUSSEL VET warrants only that the product conforms to the chemical description on the label and is responsively fit for the purpose stated on the label when used in accordance with the directors under normal conditions of use. This warranty does not estend to the use of this product contently interested to the construction or under conditions, or under conditions not rescorably loreseeable to HOECHST ROUSSEL VET, and use assumes the risk of any such use. HOECHST ROUSSEL VET MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUNIC ANY IMPLIED WARRANTY OF FITNESSED FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. Its no case shall HOECHST ROUSSEL VET be hable for consequential, appress, indirect or incidental distinges resulting from the use or handing of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duty authorized representative of HOECHST ROUSSEL VET.

Talkic (amitrax) is a registered trademark of Hoschet Roussel Vet GmbH. The name and logo HOECHST are registered trademarks of HOECHST AG.

01996 HPI Vet 584350-5:98 MADE IN CANADA NET CONTENTS: 190 tol (53.7 ft. cs.)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SEP 2 2 1998

John J. Lauber, Ph.D. Hoechst Roussel Vet P.O. Box 2500 Somerville, New Jersey 08876-1258

Dear Dr. Lauber:

Subject: Labeling Requirements for Reregistration

Tactic E.C.

EPA Reg. No. 54382-3

Your submission dated 16 September 1997

The labeling referred to above submitted in connection with reregistration under Section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, has been received and reviewed, and the following are the Agency's comments:

Precautionary Review Comments

- 1. You must include on your labeling the phrase "Contains Petroleum Distillate".
- 2. The signal word for this product is DANGER.
- 3. The precautionary statements should reflect: Corrosive. Causes irreversible eye damage. Cause skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.
- 4. The Statement of Practical Treatment (SOPT) "First Aid" should be reflected on the labeling as follows:
- 5. IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.
- 6. IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

- 7. IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to mouth. Get medical attention.
- 8. IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

It is recommended that the proposed labeling should contain a Note to Physicians with the following guidance:

NOTE TO PHYSICIAN:

The proposed label should contain.

Probable mucosal damage may contraindicate the use of gastric lavage.

May pose an aspiration pneumonia hazard.

The following are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- -technical information on symptomatology;
- -use of supportive treatments to maintain life functions;
- -medicine that will counteract the specific physiological effects of the pesticide;
- -company telephone number to specific medical personnel who can provide specialized medical advice.

Should you have any further questions regarding these amendments to your labeling, you may contact me directly at 703.305.5412.

Sincerely,

Leonard Cole

Insecticide-Rodenticide Branch

Registration Division (7505C)

DP BARCODE: D249399

CASE: 117897 DATA PACKAGE RECORD DATE: 09/11/98

SUBMISSION: S531805 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 674 8 MNTH RESP-PROD SPC DATA

RANKING : 0 POINTS ()

CHEMICALS: 106201 Amitraz (ANSI) 12.5000%

ID#: 054382-00003 TAKTIC B.C.

COMPANY: 054382 HOECHST ROUSSEL VET

PRODUCT MANAGER: 04 TINA LEVINE 703-308-7055 ROOM: CM2 219
PM TEAM REVIEWER: CP MORAN 703-308-8590 ROOM: CM2 117 L

RECEIVED DATE: 09/23/97 DUE OUT DATE: 03/22/98

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 249399 EXPEDITE: N DATE SENT: 09/11/98 DATE RET.: / /

CHEMICAL: 106201 Amitraz (ANSI)

DP TYPE: 001 Submission Related Data Package

CSF: Y LABEL: Y

ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 12/10/98
DIV: RD / / NEGOT DATE: / /
BRAN: IRB / / / PROJ DATE: / /
SECT: PM04 / / /
REVR: / / / /
CONTR: / / /

* * * DATA REVIEW INSTRUCTIONS * * *

This product is recommended for reregistration upon your final revie of the label for compliance with the Amitraz RED. After label review is done, please close this data package submission as well as the 674 submission with a reregistration decision and file all pertinent information in the product jacket.

Attached:

CSFs

Labels

Product Chemistry review

Acute Toxicity reviews

PRB preliminary label assessment

Correspondence/administrative

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
240281	TRB/IO	10/28/97	01/26/98	Y	Y	¥
240309	TRB/TOX	10/29/97	11/14/97	Y	Y	Y
241308	PRB/IO	12/04/97	03/04/98	Y	Y	Y



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

Date:

February 9, 1998

Subject:

Data review of product TAKTIC EC for acute eye irritation (81-4), and

dermal sensitization (81-6) EPA Reg. No.: 54382-3

MRID Nos.:

44388508, 44388510

DP Barcode:

D242206

From:

Hari Mukhoty, DVM, PhD (Secondary review by Ian Blackwell)

Product Reregistration Branch (PRB)

Special Review and Reregistration Division (SRRD), Mail Code: 7508W

To:

C.P. Moran, CRM

PRB, SRRD, Mail Code: 7508W

Applicant:

Hoechst Roussel Vet

P.O. Box 4915

30 Independence Blvd. Warren, NJ 07059

FORMULATION FROM LABEL:

Active Ingredient	:: % by wt.
Amitraz	12.9
Inert Ingredients.	87.1
Total	100.0

BACKGROUND:

Hoecht Roussel Vet has submitted data on primary eye irritation and dermal sensitization studies for Amitraz-based insecticide product with the trade name TAKTIC EC. The company is asking the Agency to evaluate the studies as to their acceptability in satisfying the 81-4, and 81-6 data requirements for reregistration. The data for the remaining four acute toxicity studies are currently being reviewed by the contractor on Bean Sheet No. D240309. This is a 6 (a) (2) review for primary eye irritation and dermal sensitization effects of TAKTIC EC (ISB/IRSD Request for 6 (a) (2) screen document dated October 23,1997).

RECOMMENDATION:

Studies submitted for acute eye irritation and dermal sensitization are acceptable.

The acute toxicity profile for product Reg. No. 54382-3 is currently:

Primary eye irritation

Acceptable

Dermal sensitization

Sensitizer

Acceptable

LABELING:

Labeling shall be provided when review of the remaining 4 acute toxicity studies is complete.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (Series 81-6 / 870.2600)

Product Manager: Tina Levine, 4

MRID No.: 44388510

Reviewer: Hari Mukhoty

Study completion date: August 28,1997

Report No.: 96-0029

Testing Laboratory: Springborn Laboratories, Inc.

Author: Deborah A. Douds

Quality Assurance (40 CFR Part 160.12): included

Test Material: Taktic E.C., HPA Reg. No.: 54382-3 (yellow liquid)

Positive control material: DNCB

Species: Hartley albino guinea pigs

Weight: 332-433 grams. Age: not provided

Source: Harlan Sprague Dawley, Inc.

Method: Modified Buehler method

Summary:

1. This product is a dermal sensitizer.

2. Classification: acceptable

PROCEDURE & RESULTS:

Two range-finding tests were conducted, and each test used four (2 males & 2 females) young adult guinea pigs. The first test used test material at concentrations of 25%, 50%, 75%, and 100% w/v in deionized water, and all the animals showed severe dermal irritation ranging from redness to edema. Therefore, a second test was performed with lower concentrations (5%, 10%, 15%, and 20% w/v in deionized water) of the test material. In the second test, only few animals showed slight redness of the skin.

For induction study, ten animals were topically treated with 0.3 mL of 50% w/v of the test material in deionized water, once per week, for three consecutive weeks. Following a two-week rest period, a challenge test was performed with 10 test-material induced animals and ten previously untreated challenge control guinea pigs. These animals were exposed with 0.3mi of 20% solution of test material for 6 hours. Irritation responses were scored approximately 24 and 48 hours after treatment in all three phases of both induction and challenge tests. Dermal irritation ranging from redness (slight patchy & confluent, moderate patchy & confluent) to edema was noticeable in most animals in all induction phases. Following challenge, redness (dermal scores: 1 to 2- slight patchy, slight confluent, moderate

patchy, moderate confluent) and slight edema were noted in some animals at the 24 and 48 hour scoring interval. Group mean dermal scores were noted to be higher in the test animals as compared with the challenge control animals.

DNCB control group received 0.3 mL of 0.1% w/v DNCB in acetone/ethanol for induction and 0.1% and 0.05% w/v DNCB in acetone/ethanol for challenge. Following challenge, 10/10 DNCB test animals were noted to have a substantially stronger dermal response than was observed in the corresponding DNCB control animals.

CONCLUSION:

- (a). The test product produced various degrees of dermal reaction during the induction phase (slight patchy & confluent redness, moderate patchy & confluent erythema, very slight to slight edema with edges area well defined by definite raising)
- (b). Dermal sensitization reactions, ranging from redness to edema, were observed following challenge with the test substance. Group mean dermal scores were noted to be higher in the test animals as compared with the challenge control animals.
- (c). DNCB positive control animals showed dermal reactions following each of the inductions; and positive responses occurred after challenge. Following challenge with DNCB, 10/10 DNCB test animals were noted to have a substantially stronger dermal response than was observed in the corresponding DNCB control animals.

The dermal reaction observed in this study adequately demonstrate that test product, Reg. No.54382-3, is a contact sensitizer in guinea pig. This study is classified as acceptable. This study (MRID 44388510) satisfy the 81-6 data requirement for the above referenced product.

RESULTS:

		(number "positive"/number tested)						
	Hours			·. · · · · · · · · · · · · · · · · · ·	Days			<u> </u>
OBSERVATIONS	1	24	48	72	7	10	14	21
Comeal Opacity	6/6	6/6	5/6	5/6	5/6	3/6	2/6	2/6
Iris	6/6	5/6	4/6	4/6	2/6	2/6	1/6	1/6
Conjunctivae				····				
Redness	6/6	6/6	6/6	6/6	3/6	1/6	1/6	1/6
Chemosis	6/6	6/6	5/6	5/6	2/6	1/6	1/6	1/6
Discharge	6/6	6/6	4/6	2/6	0/6	0/6	0/6	0/6

ACUTE TOX ONE-LINER

1. PC CODE:

106201

2. CURRENT DATE:

February 9, 1998

3. TEST MATERIAL: TAKTIC E.C. (Amitraz 12.9%) EPA Reg. No. 054382-3

Data for acute oral, dermal, inhalation toxicity, and skin irritation are currently being

reviewed by the contractor.

Study/Species/ Lab/Study#/Date	MRID#	Results	Tox. Cat.	Core Grade
acute oral toxicity		LD ₅₀ males mg/kg females mg/kg combined mg/kg		, u
acute dermal toxicity		LD ₅₀ > 2000 mg/kg limit test		
acute inhalation toxicity/		LC ₅₀ males mg/L females mg/L combined mg/L		
primary eye irritation/rabbit/Springborn Lab. Inc./96-0027/2-21-97	44388508	Corneal opacity resolved in 4/6 by day 14. Iritis resolved in 5/6 by day 14. Redness, chemosis & discharge at 1hr on 6/6 continued past 72 hours.	I	A
primary dermal irritation/				
skin sensitization/rabbit/Springborn Lab. Inc. /96-0029/ 3-7-97	44388510	dermal sensitizer		A

Core Grade Key:

A = Acceptable

S = Supplementary (upgradeable)

U = Unacceptable

V = self-Validated

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (Series 81-4, 870.2400)

Product Manager: Tina Levine, 4 Reviewer: Hari Mukhoty

MRID No.: 44388508 Study completion date: August 28, 1997

Report No.: 96-0027

Testing Laboratory: Springborn Laboratories, Inc.

Author: Deborah A. Douds

Quality Assurance (40 CFR Part 160.12): included

Test Material: Taktic E.C., EPA Reg. No.: 54382-3 (yellow liquid)

Dosage: 0.1 mL

Species: New Zealand White rabbits.

Weight: 332-433 grams. Age: not provided.

Source: Myrtle's Rabbitry

Summary:

1. Toxicity Category: I

2. Classification: acceptable

PROCEDURE AND OBSERVATION:

The eyes were macroscopically examined with the aid of an auxiliary light source for signs of irritation at 1, 24, 48, and 72 hours and up to 21 days after dosing according to the Ocular Grading System which is based on Draize. Fluorescein examination was also done to check the affected eyes. Some animals vocalized following dosing, and hair loss was noticed in few animals around and under the right eye.

STATED STATES TO
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Indus 6/15/98

June 12, 1998

MEMORANDUM:

Subject:

EPA Reg. No.: 54382-03/Taktic E.C.

DP Barcode: D246167

Case No.: 0234

From:

Marianne Lewis, Biologist

Product Reregistration Branch

Special Review and Reregistration Division (7508W)

To:

C.P.Moran, CRM

Product Reregistration Branch

Special Review and Reregistration Division (7508W)

Applicant:

Hoechst Roussel Vet

P.O.Box 4915

30 Independence Blvd. Warren, NJ 07059

FORMULATION FROM EPA Reg. No. 54382-03 LABEL:

	% by wt.
Active Ingredient(s):	
Amitraz (N'-(2,3-dimethylphenyl)-N-[[2,3-dimethylphenyl)imino]	
methyl]-N-methylmethanimidamide)	12.5%
Inert Ingredient(s):	87.5%
Total	100.0%

BACKGROUND: In the 8 month response to the Amitraz RED the registrant has submitted acute toxicity studies to support the reregistration of their product, EPA Reg. No. 54382-03. The MRID's are as follows: 4438850-05 (81-1), 443885-06 (81-2), 443885-07 (81-3), 443885-08 (81-4), 443885-09 (81-5), 443885-10 (81-6). The studies were conducted by Springborn Laboratories, Inc. The material used in the studies was Taktic B.C. Miticide Insecticide, EPA Reg. No. 54382-03. Four (81-1, 81-2, 81-3, 81-5) of the acute toxicity studies were reviewed for PRB by Oak Ridge National Laboratory, an EPA contractor. The primary eye irritation study (81-4) and the skin sensitization study (81-6) were reviewed and accepted by PRB/SRRD, 2/12/98. The four (81-1, 81-2, 81-3, 81-5) studies reviewed are acceptable to support the reregistration of EPA Reg. No. 54382-03.

<u>RECOMMENDATIONS</u>: All of the submitted acute toxicity studies are acceptable to support the reregistration of EPA Reg. No. 54382-03.

The procedural deviations found are discussed here:

Acute Inhalation Study (81-3): At the 2.07 mg/L dose the oxygen content of the exposure chamber was inadequate. From the data given in the study the mean air flow rate (L/min) for the 2.07 mg/L exposure was 5.98 L/min. This indicates that it would take approximately 16.72 minutes to replace the air in the chamber and for each hour during the exposure the air would be replaced only 3.59 times. The Guidelines indicate that the air in the chamber must be changed a minimum of 10 times per hour. This ensures that there is an adequate oxygen content of at least 19% in the chamber during the exposure and that the test atmosphere is evenly distributed throughout the chamber. The two doses used were not sufficient to determine the LC₅₀. However, the 2 doses bracket the Toxicity Category III so the Agency will classify this product as Toxicity Category III. Therefore, the number of air changes in the exposure chamber is a minor deviation and will not affect the outcome of the classification of this product.

The acute toxicity profile for HPA Reg. No. 54382-03 is currently:

Acute Oral	Ш	Acceptable
Acute Dermal	Ш	Acceptable
Acute Inhalation	Ш	Acceptable
Primary Eye	I .	Acceptable
Primary Dermal	П.	Acceptable
Skin Sensitization	skin sensitizer	Acceptable

LABELING:

ID#:

054382-00003

TAKTIC E.C.

RESTRICTED USE CLASSIFICATION RECOMMENDED:

Due to eye irritation toxicity category.

The PM Team should decide if restricted use classification is necessary or if alternative labeling will allay the requirement for restricted use classification.

INGREDIENT LABELING:

Contains Petroleum Distillate.

SIGNAL WORD:

DANGER

PRECAUTIONARY STATEMENTS:

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT (SOPT) "FIRST AID":

IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.

PRB recommends that the proposed label should contain a Note to Physicians with the following guidance:

NOTE TO PHYSICIAN:

The proposed label should contain.

Probable mucosal damage may contraindicate the use of gastric lavage.

May pose an aspiration pneumonia hazard.

Note to CRM/PM/Registrant:

Here are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

DATA REVIEW FOR ACUTE ORAL TOXICITY (§81-1, 870.1100)

Product Manager: Tina Levine, 04

Reviewer: Marianne Lewis

MRID No.: 443885-05

Study Completion Date: 8/28/97

Report No.: 3207.31

Testing Facility: Springborn Laboratories

Author: D.Douds

Quality Assurance (40 CFR §160.12): Included

Test Materiai: Taktic E.C.Miticide Insecticide, EPA Reg. No. 54382-3, yellow liquid

Species: Sprague-Dawley Crl: CD*BR VAF/Plus* Rat

Age: young adult

Weight: males = 245-299 g; females = 213-272 g

Source: Charles River Laboratories

Conclusion:

1. LD_{50} (mg/kg): males = 3194.8 mg/kg (2615.3-3902.7 mg/kg)

females = 2417.0 mg/kg (1984.5-2943.6 mg/kg) combined = 2837.2 mg/kg (2461.6-3270.2 mg/kg)

2. Tox. Category: III Classification: Acceptable

Procedure (Deviations from §81-1): none

Results:

<u>.</u>	Nu	mber Deaths/Number T	'ested
Dosage (mg/kg)	Males	Females	Combined
2000	0/5	1/5	1/10
3500	3/5	5/5	8/10
5000	5/5	5/5	10/10

Observations:

Dosage mg/kg	Time of Death	Observations
2000	1/10 on day 2	reduced feces, rough coat, dehydration, urine stain, dark material around eyes/nose, decreased activity, piloerection, hunched posture, no feces, low food consumption, lacrimation, slow breathing, prostration, cool to touch, hairloss, corneal opacity, distended abdomen, and fecal material in mouth
3500	2/10 on day 1 1/10 on day 2 3/10 on day 3 2/10 on day 4	decreased activity, piloerection, low food consumption, slow/shallow/labored breathing, reduced/no feces, dark material around eyes/nose/mouth, lacrimation, dehydration, urine/fecal stain, cool to touch, wobbly gait, prostration, hunched posture, rough coat, tremors
5000	3/10 on day 1 1/10 on day 2 3/10 on day 3 2/10 on day 4 1/10 on day 7	decreased activity, slow/shallow/labored breathing, lacrimation, prostration, cool to touch, piloerection, urine/fecal stain, dark material around eyes/mouth/nose, rough coat, hunched posture, low food consumption, reduced/no feces, corneal opacity, eyelids partially closed, hairloss around eyes, dehydration, cyanosis

Gross Necropsy:

Dose mg/kg	Gross necropsy observations
2000	Of the survivors; 1 had thickening of mucosa & white raised areas on stomach, 2 had hairloss, 2 had adhesion within abdominal cavity. The one animal that died had abnormal contents of the small intestine/stomach/urinary bladder and the hair coat was wet & matted.
3500	Hairloss was noted in the two animals that survived the study. The animals that died during the study had: abnormal contents of the small intestine/stomach, mottled/dark red lungs, dilated kidney, pale liver, reddened mucosa of stomach, stained stomach mucosa, dark red thymus/throid, abnormal bladder content, dark material on haircoat, wet matted haircoat.
5000	In all test animals at this dose: abnormal contents in small intestine/stomach, mottled/reddened lungs, mottled kidneys, mottled liver, reddened mucosa of stomach, dark red foci on thymus, dark red thyroid, smaller than usual thymus, dark material on haircoat, wet matted haircoat, dried material matted on haircoat.

DATA REVIEW FOR ACUTE DERMAL TOXICITY (§81-2, 870.1100)

Product Manager: Tina Levine, 04

Reviewer: Marianne Lewis

MRID No.: 44388506

Study Completion Date: 8/28/97

Report No.: 3207.32

Testing Laboratory: Springborn Laboratories, Inc.

Author: D.Douds

Quality Assurance (40 CFR § 160.12): Included

Test Material: Taktic E.C.Miticide Insecticide, EPA Reg. No. 54382-3, yellow liquid

Species: New Zealand White Rabbit

Weight: males = 2496-2679 g; females = 2344-2618 g

Age: adult

Source: Myrtle's Rabbitry

Summary:

1. LD_{50} (mg/kg): males: >2000 mg/kg

females: >2000 mg/kg combined: >2000 mg/kg

2. Tox. Category: III

Classification: Acceptable

Procedure (Deviations From §81-2): none

Results:

Reported Mortality

	(number deaths/number tested)		
DOSAGE (mg/kg)	Males	Females	Combined
2000	0/5	0/5	0/10

Observations: All test animals were unwilling to lift their head from the cage grate unless stimulated. This reaction cleared by the 24 hour observation in all test animals. Other clinical signs iocluded: slow/labored breathing, decreased activity, protruding penis, dilation of vessels in ears, tremors, reduced feces, softs stools, fecal staining, nystagmus, low food consumption, fasciculation, eyelids appeared red and partially closed, animals were cool to touch, dark material around the nose/mouth. These signs cleared in all test animals by day 6. One animal had soft/mucoid stools and fecal staining from day 6 until the end of the study (day 14).

The dermal irritation seen in all test animals throughout the study included: superficial lightening and blanching of up to 50% of the test area, formation of eschar for more than 50%

of test area, desquamation, very slight to moderate/severe erythema and very slight to slight edema. Fissuring was observed in one animal.

Gross Necropsy Findings: One animal had clear fluid filled cysts on the oviduct, however, this is a common observation in this strain of rabbit. Overall, there were no significant changes observed.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3, 870.1300)

Product Manager: Tina Levine, 04

Reviewer: Marianne Lewis

MRID No.: 443885-07

Study Completion Date: 8/28/97

Report No.: 3207.33

Testing Laboratory: Springborn Laboratories, Inc.

Author: D.Douds

Quality Assurance (40 CFR §160.12): Included

Test Material: Taktic E.C.Miticide Insecticide, EPA Reg. No. 54382-3, yellow liquid

Species: Sprague-Dawley Crl: CD*BR VAF/Plus* Rat Weight: males = 253-289 g; females = 221-256 g

Age: young adult

Source: Charles River Laboratories, Inc.

Summary:

1. The estimated LC₅₀ (mg/L) is > 0.55 mg/L

2. MMAD (0.55 mg/L): $2.0 \mu m$

GSD (0.55 mg/L): $1.8 \mu m$

MMAD (2.07 mg/L): $2.3 \mu m$

GSD (2.07 mg/L): $1.9 \mu m$

3. Tox. Category: III

Classification: Acceptable

Procedure (Deviation From §81-3):

at 2.07 mg/L exposure there were less than 10 air changes/hour

Results:

Reported Mortality

	(Number Deaths/Number Tested)			
Exposure Concentration	Males	Females	Combined	
0.55 mg/L	0/5	0/5	0/10	
2.07 mg/L	5/5	5/5	10/10	

The doses used were not sufficient to determine the LC₅₀. However, the two doses bracket the Toxicity Category III and enough information was available in this study to determine the Toxicity Category.

Chamber Atmosphere			
Dose Level	MMAD	GSD	% particles <4.0 μm
0.55 mg/L	2.0 μm	1.8 µm	89%
2.07 mg/L	2.3 μm	1.9 μm	80%

	Dose levels	
Chamber Environment	0.55 mg/L	2.07 mg/L
Chamber Volume	100 liters	100 liters
Airflow	159.29 lpm	5.98 lpm
Temperature (°F)	68.1-70.0	68.0-69.4
Relative Humidity (%)	8.6-24.1	13.5-23.0

Clinical Observations: At 0.55 mg/L, clinical signs noted in all test animals were as follows: decreased activity, wobbly gait, congested/shallow/labored breathing, rales, reduced feces, unkempt appearance, rough coat, dark material around the nose/mouth, salivation, hairloss, corneal opacity, low food consumption, hunched posture, exopthalmus, urine stains, and a raised area on one animal's abdominal region.

At 2.07 mg/L, clinical signs noted in all test animals were as follows: decreased activity, wobbly gait, congested/shallow/labored breathing, gasping, few feces, urine stain, unkempt appearance, dehydration, ocular discharge, corneal opacity, constricted pupil, exopthalmus, dark material around nose/mouth, nasal discharge, and low food consumption.

Gross Necropsy Findings: In the 0.55 mg/L group, one survivor had a clear fluid filled cyst found on the right kidney, otherwise there were no significant changes observed.

In the 2.07 mg/L group the following changes were noted: bilateral opacity, lungs dark red, stomach with abnormal contents, black grandular mucosa of the stomach, abnormal contents of the small intestine (black/greenish/tan/brown mucoid), liver mottled/pale.

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: Tina Levine, 04 Reviewer: Marianne Lewis

MRID No.: 443885-09 Study Completion Date: 8/28/97

Report No.: 3207.35

Testing Laboratory: Springborn Laboratories, Inc.

Author: D.Douds

Quality Assurance (40 CFR §160.12): Included

Test Material: Taktic E.C.Miticide Insecticide, EPA Reg. No. 54382-3, yellow liquid

Dosage: 0.5 ml

Species: New Zealand White Rabbit

Age: adult
Sex: 6 females

Weight: 2272-2434 g

Source: Myrtle's Rabbitry

Summary:

1. Toxicity Category: II 2. Classification: Acceptable

Procedure (Deviations From §81-5): none

Results: At 1 hour 5/6 had moderate to severe erythema and 1/6 had very slight erythema. At 72 hours 3/6 had moderate to severe and 3/6 had well defined erythema. At 7 days 4/6 had well defined and 2/6 had very slight erythema. Very slight to slight edema was noted in all animals from 1 bour post-exposure to day 7, clearing in all by 10 days. At day 14 3/6 cleared all erythema/edema, 3/6 had well defined to very slight erythema, and 1/6 had very slight edema. Desquamation was seen in all from day 7 until the end of the study. In 2 animals eschar formation was observed (clearing by day 10) and in 2/6 test animals grade 1 blanching & grade 1 superficial lightening was observed (clearing by day 7).

ACUTE TOX ONE-LINER

1. PC CODE: 106201

2. CURRENT DATE: June 12, 1998

3. TEST MATERIAL: Taktic B.C.Miticide Insecticide, EPA Reg. No. 54382-3,

amitraz:12.5%

Study/Species/ Lab/Study#/Date	MRID#	Results	Tox. Cat.	Core Grade
acute oral toxicity/rat/ Springborn Labs./3207.31/ 8-28-97	44388505	LD ₅₀ males = 3195 mg/kg females = 2417 mg/kg combined = 2837 mg/kg	III	A
acute dermal toxicity/rabbit/ Springborn Labs./3207.32/ 8-28-97	44388506	LD ₅₀ > 2000 mg/kg	ш	A
acute inhalation toxicity/rat/ Springborn Labs./3207.33/ 8-28-97	44388507	estimated LC ₅₀ is >0.55 mg/L	m	A
primary dermal irritation/ rabbit/Springborn Labs./ 3207.35/8-28-97	44388509	At 1 hr. 5/6 had moderate/severe & 1/6 had very slight erythema. At 72 hrs. 3/6 had moderate/severe erythema & 3/6 had well defined erythema. At 7 days 4/6 had well defined and 2/6 had very slight erythema. Very slight to slight edema in all from 1 hr. to day 7. Edema cleared in all by day 10. Desquamation seen in all from day 7 until end of study. Eschar formation, blanching, and superficial lightening also present.	II	A

Core Grade Key:

A = Acceptable

S = Supplementary (upgradeable)

U = Unacceptable

V = self-Validated

NOTE TO FILE:

There are a few alterations made to the contractor's review of EPA Reg. No. 54382-03, which include: 1) the observations in all studies were reworded, 2) added deviation to acute inhalation study, 3) changed toxicity category for the primary dermal irritation study.

DATE OUT: 30/JAN/1998

SURJECT: PRODUCT CHEMISTRY REVIEW OF Manufacturing-Use Product[], End Use Product[x] BARCODE No.: D241308 EPA RECEIVED DATE: 23/SEP/97 REG./File Symbol No.: 54382-3

MRID: 443885-01, 443885-02, & 443885-03 PRODUCT NAME: Taktic E. C.

COMPANY NAME: Hoechst Roussel Vet Action Code: 674

FROM:

Paul Horng, Chemist Paul Hours Product Chemistry Team PRB/SRRD (7508W)

TO:

C. P. Moran, CRM

Product Reregistration Branch

PRB/SRRD (7508W)

INTRODUCTION:

With this submission, the applicant, Hoechst Roussel Vet, provided the product chemistry data, CSF, a basic formulation dated 9/SEP/97, a draft label received by the Agency on 23/SEP/97, requesting FIFRA Section 4 reregistration of end-use product Taktic E.C. Reg. No. 54382-3.

FINDINGS:

- 1. A Reregistration Eligibility Decision (RED), Case # 0234, was issued in November 22, 1996 for the Technical Grade Active Ingredient (TGAI) amitraz. The generic data base supporting the reregistration of amitraz has been reviewed and determined to be substantially complete. No data gaps are cited.
- The submitted product chemistry data (MRIDs 443885-01, -02, and -03) satisfy the data requirements for Guideline Series 61, 62, and 63 (or OPPTS Series 830 Product Properties Test Guidelines). The data are in compliance with 40 CFR 158.155 to 158.190 for reregistration of this end-use product.
- 3. The submitted CSF, a basic formulation dated 29/SEP/97, is acceptable. All the active and inert ingredients claimed in the CSF are cleared for use in pesticide formulation.
- 4. Except for the minor revision required for the label, the ingredient statement, the physical/chemical hazard statement, and the storage and disposal statement on the draft label satisfy the requirements of 40 CFR 156.10.

Because amitraz is classified as a "Group C" carcinogen, the Reregistration Eligibility Decision (RED) of amitraz required product's label for the end-use product must be revised to comply with the handler personal protective equipments. To prevent the contact with amitraz from the drifts of livestock spray and splashes from the dipped-animals, the addition of " wear chemical-resistant headgear for overhead exposure" in the paragraph of PPE on product's label is required.

RECOMMENDATION:

The registrant has satisfied the product chemistry data requirements. Once the revision of the label is made, we will have no objection to reregistration of the end-use product, Taktic E.C., Reg. No. 54382-3.

REVIEW OF PRODUCT CHEMISTRY DATA:

PRODUCT NAME: TAKTIC E. C., REG. No. 54382-3

Group A: Series 830-Product Identity, Composition, and Analysis (40 CFR 158.155, .160, .165, .170, .175, and .180).

- 830-1550 Product Identity and Composition Refer to CSF.
- 830-1600 Description of Materials Used to Produce the Product Refer to CSF.
- 830-1650 <u>Discussion of Formulation Process</u> Refer to Confidential Appendix A.
- 830-1670 <u>Discussion of Formation of Impurities</u> Refer to Confidential Appendix A.
- 830-1700 Preliminary Analysis
 Refer to Confidential Appendix A.
- 830-1750 Certified Limits
 Refer to Confidential Appendix A.
- 830-1800 Enforcement of Analytical Method

The Analytical Method (NA-A60) is a Gas Chromatography (GC) method with squalene as an internal standard. The method was validated for use in Subdivision D Product Chemistry studies with Taktic EC. Excellent accuracy and precision were demonstrated. An overall recovery of 100.0% was obtained for the nine formulation replicates ranging in concentration from 9.95% to 14.9% (wt./wt.) with a standard deviation of 0.725%. The analytical method is determined as adequate and support the reregistration of the end-use product.

Group B: Series 830- Physical and Chemical Properties (40 CFR 158.190) MRID: 443885-03

GUIDELINE REFERENCE NO.(GRN)/TITLE 830-	VALUE OR QUALITATIVE DESCRIPTION /METHOD(S) USED WHERE APPLICABLE AND REFERENCES
-6302 Color	Not required as per PR Notice 92-5.
-6303 Physical States	Clear liquid.
-6304 Odor	Not required as per PR Notice 92-5.
-6314 Oxidation/Reduction: Chemical Incompatibility	The product did not show significant oxidizing or reducing action with the water, zinc, NH ₄ H ₂ PO ₄ , KMnO ₄ and turpentine.
-6315 Flammability/ Flame Extension	Flash point 40.2 ± 0.9°C by Pensky-Martens closed cup test.
-6316 Explodability	N/A, product does not possess explosive potential.
-6317 Storage Stability of the Product	No significant change in concentration after 3 month of storage at 40°C.
-6319 Miscibility	N/A, this product is not intended to be diluted with petroleum distillates.
-6320 Corrosion Characteristics	Not corrosive to the electrolytic tin plate in a 7-days test at $40 \pm 1^{\circ}$ C.
-6321 Dielectric Breakdown Voltage	N/A, product is not to be used around electrical equipment.
-7000 pH	8.54 ± 0.09 for 1% by volume of test substance at 23.03 \pm 0.15°C.
-7100 Viscosity	4.7 ± 0.0 cp at 60 rpm and 4.44 ± 0.0 cp at 100 rpm at 25.5 ± 0.1 °C.
-7300 Density/Relative Density/ Bulk Density	Density 0.9146± 0.0001 g/cm ³ at 24.9 ± 0.2°C. Bulk density 7.5 lbs / gal.

N/A: not applicable.

Manufacturing process information may be entitled to confidential treatment

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Confidential Appendix A

830-1550 Product Identity and Composition.

This end-use product contains 12.5% active ingredient amitraz and 87.5% inert ingredient.

830-1600 Description of Materials Used to Produce the Product.

Refer to the CSF.



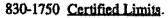
830-1670 Discussion of Formation of Impurities.

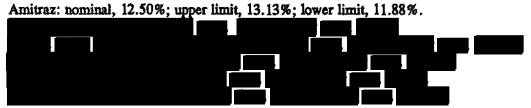


830-1700 Preliminary Analysis.

Five batches of Taktic EC were analyzed in triplicate for the active ingredient amitraz using the Enforcement Analytical Method, the results indicated the mean amitraz concentrations are $12.3 \pm 0.00\%$, $12.5 \pm 0.12\%$, $12.4 \pm 0.17\%$, $12.4 \pm 0.06\%$, and $13.0 \pm 0.10\%$. The overall recovery for the fortification samples was 102%, with an overall standard deviation of 0.814%, and precision of 0.798%. No interferences were noted during the analysis.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

9/9/98

MEMORANDUM:

Subject:

Tactic ® E.C.

EPA Reg. 54382-03

Re: PRB Preliminary Label assessment

From:

John L. Dupuy Ph.D

Product Reregistration Branch

Special Review and Reregistration Division (7508W)

Through

Lawrence Schnaubelt Lawrence Schnauber 9/10/98

Product Reregistration Branch

Special Review and Reregistration Division (7508W)

To:

Tina Levine

Branch Chief

Registration Division (7505C)

BACKGROUND: Hoechst Roussel Vet has submitted 5 copies of draft labeling for the subject product in its 8 month response to the Amitraz RED. PRB has completed a preliminary assessment of the draft labeling. In its assessment, PRB has considered the following: 1) Labeling requirements specified in the Amitraz RED; 2) Labeling specified or required in the Product Chemistry and Acute Toxicity Reviews for the subject product; and 3) Labeling requirements as specified in 40 CFR Part 156.10 and associated labeling policy documents such as the Label Review Manual or Pesticide Regulation Notices (PRNs). In addition, PRB has included recommendations to improve the comprehension and consistency of all product labels. A copy of this assessment may be accessed electronically on the Lan through the Q:Drive in Word Perfect. The path is q:\prb\label\054382\003.

NOTE: This preliminary assessment contains recommendations intended to assist Product Managers in their final review of the pesticide label. Product Managers are encouraged to use all or portions of this assessment and then apply their own knowledge of the subject product and the product's regulatory history (including comparison with existing stamped accepted labeling) to conduct a final review of the label. It is the responsibility of the PM to attain the necessary label improvements required for final product reregistration.

SUMMARY OF FINDINGS:

I RED Risk Mitigation:

The subject product label does not contain risk mitigation labeling requirements as specified in the RED.

- * The baseline PPE must be modified.
- * The statement "Follow manufacture's instructions etc." should be placed directly below the PPE.

Refer to Appendix I and III for further details.

II Technical Review Requirements:

Product Chemistry: Based on the Product Chemistry Review by Paul Horng, dated January 30, 1998, the Physical and Chemical Hazards and Storage and Disposal statements cited on the product label are acceptable. The Ingredients labeling must be modified as specified in the Acute Toxicity Review and in Appendix I.

Acute Toxicity: Based on the Acute Toxicity Review by Marianne Lewis dated June 12,1998, the following changes are required:

* Ingredient labeling must be modified as specified in Appendix I.

- * The statements appearing under "Statement of Practical Treatment" must be modified as specified in Appendix I.
- * The statements appearing under "Hazards to Humans and Domestic Animals" must be modified as specified in Appendix I.
- * Restricted Use Classification Recommended: Due to eye irritation toxic category I.

Refer to Appendix I for further details.

III Other Labeling Requirements:

The subject product contains the required labeling as specified by 40 CFR Part 156.10, PR Notices and the Label Review Manual except for the following statement.

* The Statement "Do not apply this product.....etc." must be placed in the Directions for Use. See Appendix I for further details.

Directions for Use:

For purposes of clarity and consistency, PRB recommends that the Registrant make the following changes:

- * The Storage and Disposal text should be enclosed in a box and must be placed under Directions for Use.
- * A sub-title, General Instructions and Information should be placed below the Storage and Disposal box.
- * The Directions for Application should be in a Table Format.

See Appendix I, II, and III for further details.

RECOMMENDATIONS:

The subject product label conforms with the RED, Technical Review and Agency label policies except for the comments specified above, and below in Appendices I, II and III.

Appendix I For the Product Label Tactic ® E.C. EPA Reg.No.54382-03

PRB Label Analysis

Label Requirement	Acceptable	Not Acceptable	Comments/Recommendations
Restricted Use Pesticide		x	PRB recommends that Tactic * EC be labeled a Restricted Use Pesticide. Refer to Attachment 2. The PM should consider and decide whether this is a Restricted Use Label based on the Acute Toxicity studies(Primary Eye, Toxicity Category I) and Attachment 2.
Product Name	Х		
Company Name and Information	X		
Identification Numbers	X		
Ingredients Statement		Х	The statement "This product contains xylene-range solvents" must be replaced with "Contains Petroleum Distillate."
(KOROC)	Х		
Signal Word	X		
	General He	ading "Preca	ttionary Statements"

First Aid		, X	The "Statement of Practical Treatment" or First Aid and its text should be placed directly under the heading Precautionary Statements. The Statement of Practical Treatment must be revised as follows: * IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention. * IF ON SKIN: Wash with plenty of soap and water. Get medical attention. * IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Get medical attention. * IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention. NOTE TO PHYSICIAN: The proposed label should contain: Probable mucosal damage may contraindicate the use of gastric lavage. May pose an aspiration pauemonia hazard.	
Hazards to Human and Domestic Animals	X			
Precautionary Statements		X	The Precuationary Statements must be changed to read as follows: Corrosive. Causes irreversable eye damage. Causes skin irritation. Harmful if swallowed or absorbed through the skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated cloathing and wash clothing before reuse.	

		······································	
PPE		x	The PPE must be changed to read as follows:
			Applicators and other handlers must wear: * Chemical-resistant apron over long-sleaved shirt and long pants * Chemical-resistant footwear plus socks * Chemical-resistant gloves * Chemical-resistant headgear for overhead exposure * Chemical-resistant apron when cleaning equipment, mixing, or loading. Refer to the Red(Chapter 5) and Attachment 1 The statements "Do not apply this productarea during application" must be moved and should be placed directly under the statement: "It is a Violation of Federal" in the Directions for Use. Refer to Appendix III. The statements "For livestock spraywell-ventilated areas." should be moved to the Directions For Use and placed directly under General Precautions and Restrictions under the sub-header General Instructions and Information. Refer to Appendix III.
User Safety Requirements	X		"Follow manufacturers instructionsfrom other laundry" should be placed directly below the PPE section.
Engineering Controls (if required)	N/A		
User Safety Recommendations		X	"User Safety Recommendations" and its text must be enclosed in a box.
Environmental Hazards	X		
Physical and Chemical Hazards	X		
	Directions 1	or Use (PIFRA	Text, WPS and Storage and Disposal)
Header "Directions for Use"	X		
Violation of Federal Law Text	X		
WPS Text	N/A		
Non-WPS Text	N/A		

Storage and Dispesal		X	The specific directions for Storage and Disposal of the pesticide and its container must appear under the Directions for Use. For clarity and consistency, PRB recommends that the "Storage and Disposal" and its text enclosed in box should be placed directly below the statement "It is a violation of Federalwith its labeling." in the Directions for Use.
	Directions	for Use ((Jeneral Instructions and Information)
General Instructions and Information Sub-Header	x		For clarity and consistency, PRB recommends that the sub-heading General Instructions and Information should be placed directly below the Storage and Disposal statements
Chemigation/Prohibition (if applicable)	N/A		
Spray Drift Labeling (if applicable)	N/A		
General Information (non-site specific information on uses, pests, mixing and loading, tank mixing, etc)	X		For clarity and consistency, PRB recommends that any non site specific information be placed under the sub-heading General Information.
General Precautions and Restrictions	х		For clarity and consistency, PRB recommends that "Do not useor other solvents" be moved from its present position and placed directly under the sub-heading General Precautions and Restrictions.
	Direct	tion for C	se (Directions for Application)
Sub-Header: Directions for Application	X		For clarity and consistency, PRB recommends that Directions for Application be placed above the specific sites. In addition the Direction for Applications would be clearer in the Table Format. See Appendix II for an example.
		W	erranty information
Consistency with label instructions	x		
Not false and misleading	х		
General Comments			

APPENDIX II

DIRECTIONS FOR APPLICATION

SITE	TARGET PESTS	DOSE	SPECIAL DIRECTIONS
BEEF, and DAIRY CATTLE	TICKS:*Lone Star Tick (Amblyomma americanum) *Gulf Coast Tick (A.maculatum) *Winter Tick (Dermacentor albipictus) *Brown Dog Tick (Rhipicephalus sanguineus) *American Dog Tick (D	760 ml (one can) in 100 gallons of water	Spray: Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Star ticks, Cattle ticks, Sucking lice, and Chewing lice, particular attention should be given to the legs, axilla and groin area, udder, tail regions and head including the ears. For Gulf Coast ticks and Ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice from hatching. Spray Dip Machine: Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. To control cattle scabies, applications should be made as instucted by USDA, APHIS, VS bulletins. Two treatments, 7-10 days apart are required to control cattle scabies.

SITE	TARGET PESTS	DOSE	SPECIAL DIRECTIONS	
	MITES: *Scab and Mange Mites (Chorioptes bovis, Psoroptes ovis Sarcoptes scabiel var. bovis)	760 ml (One can) in 50 gallons of water	Spray: Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. Spray Dip Machine: Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. To control cattle scabies, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments, 7-10 days apart are required to control cattle scabies.	
	Use Tactic * solutions within 6 hou	rs of mixing.		
SWINE	Mange Mites and Louse (Sarcoptes acabiei yar. suis and Haematopinus suis)	760 ml (one can) in 50 gallons of water Equivalent to ½ fl. ounce per gallon of spray solution	Spray: A sprayer with a coarse nozzle delivering the solution (1/2 fl. ounce per gallon of spray solution) at 70 to 150 psi is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jowls, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until run-off. A second treatment is recommended to break the parasites' life cycles. Make the application 7-10 days after first for mite control, and 10-14 days for lice control. Dip: An alternate to spraying young pigs(piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.	
	Important: Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use Tactic * solutions within 6 hours of mixing.			
	Restrictions: Do not treat animals more than 4 times per year.			
į	Do not apply to swine within three days of slaughter. Do not use Tactic ** E.C. at the same time with any other amitraz containing			
	product.	E.C. at the	same time with suly other amitian containing	

Appendix III

Recommended Presentation of Label

RESTRICTED USE PESTICIDE

Product Name
Ingredients
EPA Registration and Establishment Numbers
Company Name, Address, Phone Number
Net Contents
KEEP OUT OF REACH OF CHILDREN
SIGNAL WORD

PRECAUTIONARY STATEMENTS

FIRST AID

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

PPE

USER SAFETY RECOMMENDATIONS

ENVIRONMENTAL HAZARDS

PHYSICAL AND CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a Violation of Federal Law.....

Do not apply this product in a way.... Only protected handlers may be in the area....

STORAGE AND DISPOSAL

GENERAL INSTRUCTIONS AND INFORMATION

General Information (non-site-specific)

General Precautions and Restrictions

DIRECTIONS FOR APPLICATION (site-specific)

Directions for Application

WARRANTY STATEMENT

RECOURSE FOR 6(2) (2) SCREEN ACCOUNTY	
The golds for the grant of the state of the	•
product for	
SKKB Skely and	.)
Information Services Branch	1
Pocument Management Section/ISB/IRSD Induct Dile -	101
TO: Bill Burnam(HED - Tox, Onco, Residue, Prod. Chem) Jerry Blondell (HED - Animal Safety, Human Health) tan Blackwell (RD - Products - Acute Tox) Bill Schneider (BPPD) Nini Jordan(EFED) Tim McMahon (AD - Acute Tox) Srini Gowda (AD - Efficacy))
Attached are copies of transmittal letters and/or study conclusions of recently received 6(a)(2) data submissions. Please screen this information and provide me with the results by hand/mail/fax delivery of this screen cover sheet with your comments to me in Room 216 CM2 (7502C', Fax: 703/305-7670.	
PRODUCT REGISTRATION NUMBER -54382-3	
CHEMICAL NAME AMINOS - TAKTIC ER Metrodo Ansochendo	
DESCRIPTION Rumany Eye Isselving : Rebbits	
Briefly describe the reported adverse effect: Comeal opacity. Permanent eye damage	
Does this submission warrant an expedited review? Ves No SLA	··
If yes. explain: Will change precautionary statements 32073	9
for eye initation. Will change signal word to dang	
Expedited review is appropriate if the results change our regulatory position on this chemical or product. Examples are:	
Acute Tox - label change or a change tox category	
If end point is more sensitive than current basis for regulatory position	
Anticrobial Product Efficacy Failure - Label change: reduced claims or dosage increased	
158.134 Flagging Statement is positive	
If expedited, recommended timeframe for review:	
other comments: 8 mm thy Response to les - hodget Rocegistheten	J
Please respond by 10/28/97 - ig Possible	
0 (10 -80 0) 900 (0-100	



REQUEST FOR 6(a)(2) SCREEN

SRRD Scrus) ?

10/23/97 DATE:

FROM: Kathleen O'Malley

Information Services Branch

Document Management Section/ISE/IRSD

TO:

__Bill Burnam(HED - Tox, Onco, Residue, Prod. Chem) Jerry Blondell (HED - Animal Safety, Euman Health)

Ian Blackwell (RD - Products - Acute Tox)

Bill Schneider (BPPD) Nini Jordan (EFED)

Tim McMahon (AD - Acute Tox)

Srini Govda (AD - Efficacy)

Attached are copies of transmittal letters and/or study conclusions of recently received 6(a)(2) data submissions. Please screen this information and provide me with the results by hand/mail/fax delivery of this screen cover sheet with your comments to me in Room 216 CM2 (7502C), Fax: 703/305-7670.

44388510 IDENTIFICATION NUMBER

PRODUCT REGISTRATION NUMBER

CHEMICAL NAME AMILYING - TAKTIC EL MILICIDI

Dermal Sensole govern - Buelo Mexica

Briefly describe the reported adverse effect:

Topical (dermal sensitization)

Does this submission warrant an expedited review? ___ Yes____ No

It yes, explain: The label will then display & precautionary statement for dermal sensitization.

Expedited review is appropriate if the results change our regulatory position on this chemical or product. Examples are:

Acute Tox - label change or a change tox category

If end point is more sensitive than current basis for regulatory position

Anticrobial Product Efficacy Failure - Label change: reduced claims or dosage increased

158.134 Flagging Statement is positive

If expedited, recommended timeframe for review:

Other Comments: Rispose to de Juna LED

White - EPA File Copy (original)

Yellow - Applicant cog

EPA Form 8570-1 (Rev. t2-90)

Previous aditions are obsolete.

United States Environmental Protection Agency Washington, DC 20460

Form Approved OMB No. 2070-0060 Approval Expires (1-30-93

SEPA Certification with Respect to Citation of Data

Apparats Name and	Ad	dress
Hoechst Rouss	el	Vet
P.O. Box 4915		
Warren, N.J.	0	7059

EPA File Symbol/Registration Number 54382-3 Product Name Taktic Emulsifiable Concentrate Miticide/Insect. Data of Application

Sept. 16, 1997

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27). 4.50

- 1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of aproposal of this application. (Check the appropriate boxes, in items 2 and 3 below, that pertain to your application.)
- 2. I certify that, for each study cited in support of this application for registration that is an exclusive use study,
 - [X] I am the original submitter"; or
 - 1 I have obtained the written permission of the original data submitter to cite that study*
- I certify that, for each study cited in support of this application for registration that is not an exclusive use
 - a. | I am the original data submitter*; or
 - I have obtained the written permission of the original data submitter to cite that study*; or
 - b. | I have notified in writing the companies that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)
 - All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)
 - 1 Those companies that have submitted the studies which I have cited (Selective method*).
 - * A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method.)

gnalure	Lauler	Name and Title John J. Lauber, Ph.D Manager, Product Registration	Dale Sept. 16,	1997
	General Offer to Pa	y: I hereby offer and agree to pay compensation	on to Other	

persons, with regard to the approval of this application, to the extent required.

nature	Name and Title	Date

Attachment 2

Hoechst

Hoechst Roussel Vet

38 independence Bivd. © PO Box 4816 © Warran, New Jarsey 97866

Telephone: 900/231-2000

FACSIMILE MESSAGE

TO:

Mr. James S. (Steve) Morrill

DATE:

July 28, 1998

Tel:

Fax: 703-308-8041

FROM:

Jack Lauber

Tel: (908) 231-3426 Fax: (908) 231-4462

Subject: Taktic® EC, EPA Reg. No. 54382-3

Dear Mr. Morrill:

Thank you for your telephone call today concerning Taktic EC.

In Hoechst Roussel Vet's 8-month amitraz reregistration response concerning the labeling for Taktic EC, we requested waivers for the requirements for chemical resistant headgear and coveralls. In Mr. Walter Waldrop's April 13, 1998 letter, he responded to our waiver requests (see attached letter).

Chemical Resistant Headgear – Mr. Waldrop Indicated that it would be prudent to retain the use of headgear for overhead exposures. We interpreted this to mean that the Agency was requiring the current label statement, "wear a hat" rather than the more restrictive statement indicated in the amitraz RED, "wear chemical resistant headgear".

<u>Coveralls</u> In lieu of RED requirement for "coveralls over long sleeved shirt and long plants", Mr. Waldrop indicated that the substitute phrase, "chemical resistant apron over long sleeved shirt and long parts" could be used.

During our telephone conversation, we talked also about <u>restricted use classification</u> for Taktic EC. Briefly, we do not feel that restricted use classification is appropriate for Taktic EC. This is because the proposed Taktic EC label states that applicators and other handlers must wear goggles or face shields. The use of goggles or face shields would adequately protect livestock producers, who for the most part, are not certified applicators.

If you have any questions or if I can be of further help, please do not hesitate to call.

Sincerely yours,

John J. Lauber, Ph.D.

Manager, Product Registration

Attachment

980728e

Page 1 of



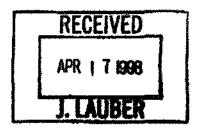
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

FIHAchnest I

APR 13 1998

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

John J. Lauber
Manager, Product Registration
Hoechst Roussel Vet
30 Independence Blvd.
P.O. Box 4915
Warren, NJ 07059



Subject:

Amitraz Reregistration

Waiver for Requirement for Coveralls and Headgear

Your letters dated 9/16/97 and 1/28/98

Dr. Lauber:

The Agency has reviewed your requests to waive the requirement for coveralls and headgear for your products registered for use on livestock. Until we receive exposure data to better define the risks associated with use of amitraz to applicators and handlers treating livestock, we believe it prudent to require that end-use product labels retain the use of headgear for overhead exposures. This is especially important for your product Taktic (Reg. No. 54382-3) where, according to your directions for use, walls and any fittings in an animal pen may be treated and may result in overhead exposures.

With regard to the request to waive the requirement for coveralls for the livestock uses, the Agency believes that similar protection would be provided with the use of an apron during application. Thus, in lieu of coveralls over long sleeved shirt and long pants for livestock uses you may substitute with a chemical-resistant apron over long sleeved shirt and long pants.

If you have any questions concerning this letter, please contact Judy Loranger at (703)-308-8056.

Sincerely yours,

Walter I. Waldrop, Chief

Reregistration Branch III

Special Review and Reregistration Division

Attachment 2

Hoechst ^a

Hoechst Roussel Vet

30 Independence Blvd. • PO Sox 4816 • Warren, New Jersey 07859

Telephone: 908/231-2000

FACSIMILE MESSAGE



TO: Mr. James S. (Steve) Morrill

DATE:

July 28, 1998

Tel:

Fax: 703-308-8041

FROM:

Jack Lauber

Tel: (908) 231-3426 Fax: (908) 231-4482

Subject: Taktic® EC, EPA Reg. No. 54382-3

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If you have any questions or if I can be of further help, please do not healtate to call.

Sincerely yours,

John J. Lauber, Ph.D.

Manager, Product Registration

Attachment

980728e

Page 1 of

: 3/19/98 20

Hoechst Roussel Vet

Hosehst Roussel Vet 30 Independence Blvd. P.O. Box 4915 Warren, NJ 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mell JLauber@HRVet.com

March 13, 1998

Document Processing Desk (RED-SRRD-0234)
Office of Pesticide Programs (H7504C)
Att. C.P. Moran
Special Review and
Reregistration Division
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

Subject: Amitraz Reregistration

Dear Mr. Moran:

Thank you very much for faxing me the February 9, 1998 Review of Taktic® EC acute eye irritation and dermal sensitization. I appreciated receiving this information.

As I mentioned in my letter of January 28, 1998 (copy attached), we need guidance from the Agency concerning the required label text for Taktic EC and Point-Guard ™ Miticide/Insecticide. The following, requiring Agency acceptance, have a direct bearing on the finel label text of these two products:

- · coveralls label waiver request
- chemical resistant headgear for overhead exposure label waiver request
- remaining Taktic EC product toxicology studies
- draft labeling

May I hear from you soon concerning this matter? Thank you in advance for your help.

Sincerely yours;

John J. Lauber, Ph.D.

Manager, Product Registration

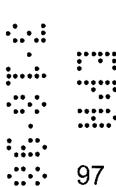
Attachment

980313b

Hoechst '

Hoschet Roussel Vet

A member of the Hoschat Group



Hoechst Roussel Vet

Hoschat Roussel Vet 30 Independence Bivd. P.O. Box 4915 Warren, NJ 07059

Telephone (908) 231-3426 Fax (908) 231-4462 E-mell JLauber@HRVet.com

January 28, 1998

*

Document Processing Desk (RED-SRRD-0234)
Office of Pesticide Programs (H7504C)
Att. Mr. Walter I. Waldrop
Special Review and
Reregistration Division
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

Subject: Amitraz Reregistration

Dear Mr. Waldrop:

The purpose of this letter is to inquire about the status of the Agency review of the following which have a direct bearing on the labeling of Taktic EC and Point-Guard Miticide/Insecticide required in 1999 by the amitraz RED:

- draft labeling
- · coveralls label waiver request
- chemical resistant headgear for overhead exposure label waiver request
- Taktic EC product toxicology studies

Background

Hoechst Roussel Vet (HR Vet) is the registrant of two amitraz products used on cattle and swine. The products are Taktic® Emulsifiable Concentrate Miticide/Insecticide (Taktic EC) (EPA Reg. No. 54382-3) and Point-Guard™ Ready-To-Use Miticide/Insecticide (Point-Guard Miticide/Insecticide) (EPA Reg. No. 54382-6) (Previously Known as Taktic® Linebacker Pour-On).

Hoechst "

Hoechst Roussel Vet A member of the Hoechst Group On September 16, 1997, HR Vet submitted to the Agency draft labeling for Taktic EC and Point-Guard Miticide/Insecticide. As you know, the amitraz RED requires HR Vet to begin to distribute and sell products with revised labeling on or before March 17, 1999. Product with old labeling cannot be distributed or sold. Since HR VET will be producing these products later this year, we need guidance from the Agency concerning required label text.

Draft Labeling

Draft labeling for Taktic EC and Point-Guard were submitted with our letters, dated September 16, 1997 and October 21, 1997. We incorporated all of the required label changes, except for the requirement for the applicators of Taktic EC to wear coveralls and chemical resistant headgear.

Coveralls Label Waiver Request

A waiver request for the requirement of coveralls was submitted with our letters dated April 3, September 16 and October 21, 1997. Briefly, our waiver request was based on the fact that the Agency overestimated the exposure to amitraz to farmworkers using Taktic EC, and that minimal personal protective equipment will adequately protect farmworkers from either acute or chronic risk of exposure to amitraz used on livestock.

Chemical Resistant Headgear for Overhead Exposure Label Waiver Request

The requirement for chemical-resistant headgear for overhead exposure is inappropriate for Personal Protective Equipment for both Taktic EC and Point-Guard, as both of these products are not used in an overhead exposure situation.

A Taktic EC label waiver request for the requirement of chemical resistant headgear for overhead exposure was submitted with our letter dated September 16, 1997. This requirement seems applicable to pesticides applied in an orchard crop situation (an overhead exposure situation), and not to the situation with Taktic EC which is a product applied as a spray, dip, or in a spray dip machine for control of ticks, lice and mites on swine and cattle.

A Point-Guard Miticide/Insecticide label waiver request for the requirement of chemical resistant headgear for overhead exposure was submitted with our letters dated September 16 and October 21, 1997. This requirement seems applicable to pesticides applied in an orchard crop situation (an overhead exposure situation).



Point-Guard Miticide/Insecticide is an insecticide applied on swine at a specified dose to control lice and mange mites. Point-Guard Miticide/Insecticide is supplied as a 3000 ml-container which is intended to be carried as a backpack. No water or other liquid is mixed with Point-Guard Miticide/Insecticide. Before application, the 3000 ml-backpack is quickly and easily connected to the applicator gun. The applicator gun has been specially designed and constructed to give continued accurate dosing with the product. The assembled backpack and applicator gun become in effect a "closed system", which does not need to be disconnected for storage. Point-Guard Miticide/Insecticide is directed downwards from the applicator to the pig, and is delivered as a liquid stream, rather than as a spray. Depending upon the size of the pig, only 5 ml to 135 ml of Point-Guard Miticide/Insecticide is delivered to each ear of the pig and along the dorsal midline from between the ears to the rump of the animal. The product is not applied to the entire animal because the Point-Guard Miticide/Insecticide has been specially formulated to spread by itself over the body of the animal after application. Point-Guard application is without product waste, which often occurs when using sprays and dips. Because of Point-Guard's closed application system, there is no mist or spray that the applicator is exposed to.

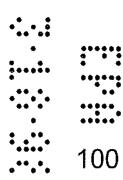
Taktic EC product toxicology studies

The results obtained in the new product toxicology studies for Taktic EC indicated that the product is a severe eye irritant and causes skin sensitization. Consequently, in conformance with 40 CFR 156.10, label changes have been made, including the change in the signal word from "Caution" to "Danger".

In conclusion, we would appreciate learning from the Agency the status of the review of the draft labeling, label waiver requests for coveralls and chemical resistant headgear, and the new Taktic EC product toxicology studies. Thank you in advance for your help.

Sincerely yours,

John J. Lauber, Ph.D. Manager, Product Registration



Hoechst Roussel Vet

Hoechst Roussel Vet Route 202-206 PO Hax 2500 Somerville, NJ 08876-1258 Telephone (908) 231-2000

Direct line (908) 231-3426

April 9, 1997

Mr. C. P. Moran, Chemical Review Manager Product Reregistration Branch Special Review and Reregistration Division (7508W) Office of Pesticide Programs Environmental Protection Agency 401 M Street, SW Washington, DC 20460

Subject: Reregistration Eligibility Decision, Amitraz, Case 0234 90 day response - product specific

Dear Mr. Moran:

Hoechst Roussel Vet (HRV) is the registrant of two amitraz products used on cattle and swine. The products are Taktic® Emulsifiable Concentrate Miticide/Insecticide (Taktic EC) (EPA Reg. No. 54382-3) and Point-Guard TM Ready-To-Use Miticide/Insecticide (Point-Guard Miticide/Insecticide) (EPA Reg. No. 54382-6) (Previously Known as Taktic® Linebacker Pour-On).

On January 17, 1997, HRV received the Amitraz Reregistration Eligibility Decision (RED) by certified mail. As per the instructions that accompanied the RED, we are making our 90-day response (product specific) with this letter and are enclosing the completed "Data Call-In Response" and "Requirements Status and Registrant's Response".

Also, in regard to the Amitraz RED, we are submitting the following under separate cover: a request for waiver of the coveralls label requirement.

If you have any questions, or require additional information, please do not hesitate to call me at 908-231-3426.

Sincerely yours,

John J. Lauber Ph.D.

Manager, Product Registration

Certified Mail (P 205 871 890), Return Receipt Requested

Hoschst Roussel Vet
A member of the Hoechse Group



Taktic®

EMULSIFIABLE CONCENTRATE MITICIDE/INSECTICIDE

FOR THE CONTROL OF TICKS, MANGE MITES AND LICE ON BEEF CATTLE, DAIRY CATTLE AND SWINE

DO NOT USE ON HORSES. MAY CAUSE FATAL COLON IMPACTION.

EPA Reg. No. 54382-3 EPA Est No. 045639-CAN-001 U.S. Patent Nos. 3,781,355 and 3,864, 497

Hoechst Roussel Vet

30 Independence Blvd. Warren, NJ 07059

Hoechst "

Hoechst Roussel Vet A member of the Hoechst Group

ACTIVE INGREDIENT:	Percent by Weight
Amitraz (N'-(2,4-dimethylphenyi)-N-	
[[2,4-dimethylphenyl)imino]methyl]-	
N-methylmethanimidamide)	12.5
INERT INGREDIENTS:	87.5
TOTAL	100.0

This product contains xylene-range solvents.

PRECAUCION AL USUARIO: Si usted no lee Inglés, no use este producto hasta que la etiqueta haya sido explicado ampliamente.

(TO THE USER: If you cannot read English, do not use this product until the label has been fully explained to you.)

KEEP OUT OF REACH OF CHILDREN DANGER-PELIGRO CAUTIONPRECAUCION STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: DO NOT INDUCE VOMITING. CALL A PHYSICIAN OR POISON CONTROL CENTER IMMEDIATELY. IT IS PREFERABLE TO USE GASTRIC LAVAGE UNDER MEDICAL SUPERVISION DUE TO ASPIRATION HAZARD. DO NOT INDUCE VOMITING OR GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON.

AMITRAZ IS NOT AN ORGANOPHOSPHORUS COMPOUND. DO NOT USE ATROPINE AS AN ANTIDOTE.

IF IN EYES: FLUSH WITH PLENTY OF WATER. GET MEDICAL ATTENTION IF IRRITATION PERSISTS.

IF ON SKIN: WASH WITH PLENTY OF SOAP AND WATER. GET MEDICAL ATTENTION IF IRRITATION PERSISTS.

PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animals)

DANGER CAUTION

Causes eye damage. Do not get in eyes. Harmful if swallowed, inhaled or absorbed through skin. Repeated skin contact may cause an allergic reaction in certain individuals. Avoid breathing vapors or spray mists and avoid contact with skin or clothing.

Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Harmful If absorbed-through-skin. Avoid-contact with skin, eyes or clothing.

Causes moderate eye-irritation.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

Long-sleeved shirt and long pants

Chemical-resistant footwear plus socks.

Chemical-resistant gloves

Goggles or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside.
 Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product.
 Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This preduct posticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to fish aquatic organisms in adjacent

sites... Do not contaminate water by sleaning of equipment or disposal of equipment when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Store in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposai. Pesticide wastes are toxic, improper disposai of excess pesticide, spray mixture or rinsate is a violation of federal isw. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Ageny, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

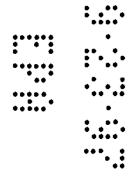
in case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER.

EMERGENCY PHONE NOS.:

HUMAN, FIRE, SPILLS, ENVIRONMENTAL: 1-800-228-5635, Ext. 132

ANIMALS: 1-800-345-4735, Ext. 104



DIRECTIONS FOR USE

it is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES or DOGS - CAN CAUSE DEATHS

DO NOT OPEN CONTAINER UNTIL READY TO USE.

USE TAKTIC[®] E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.

BEEF AND DAIRY CATTLE

TAKTIC[®] E.C. can be used on lactating dairy animals, with no withholding period for milk following application. Also, there is no post-treatment slaughter interval on beef and dairy cattle.

TICKS AND LICE:

TAKTIC[®] E.C. will control the following Ticks and Lice on cattle:

Lone Star Tick (Amblyomma americanum)

Gulf Coast Tick (A. maculatum)

Winter Tick (Dermacentor albipictus)

Brown Dog Tick (Rhipicephalus sanguineus)

American Dog Tick (D. variabilis)

Rocky Mountain Wood Tick (Dermacentor andersoni)

Spinose Ear Tick (Otobius megnini)

Black-legged Tick (ixodes scapularis)

Tropical Bont Tick (A. variegatum)

Cayenne Tick (A. cajennense)

Solenopotes capiliatus)

Cattle Tick (Boophilus annulatus)

Southern Cattle Tick (B. microplus)

Biting Louse (Demalinia bovis)
Sucking Lice (Haematopinus eurystemus, Linognathus vituli.

MITES

Scab and Mange Mites (Chorioptes bovis, Psoroptes ovis and Sarcoptes scable) var. bovis)

Spray:

For control of ticks and lice, mix one can (760 ml) of TAKTIC[®] E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC[®] E.C. in 50 gallons of water. **Use Taktic[®] solutions within 6 hours of** mixing. **Use** up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Star ticks, cattle ticks, sucking lice and chewing lice, particular attention should be given to the legs, axilia and groin area, udder, tail regions and head, including the ears. For Gulf Coast ticks and ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill lice hatching from eggs.

Spray Dip Machine:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scables, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments 7-10 days apart are required to control cattle scables. Use Taktic® solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.

SWINE

MANGE MITE AND LOUSE (Sarcoptes scable) var. suis and Haematopinus suis):

IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use TAKTIC⁶ solutions within 6 hours of mixing.

Spray:

Mix one can (760 ml) TAKTIC® E.C. in 50 gallons of water (equivalent to 1/2 fl. ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 psi is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jowi, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until run-off. A second treatment is recommended to break the parasiles' life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 days for lice control.

An alternate to spraying young pigs (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use Taktic[®] E.C. at the same time with any other amitraz containing product.

NET CONTENTS: 760 ml (25.7 fl. oz.)

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. HOECHST ROUSSEL VET warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions. or under conditions not reasonably foreseeable to HOECHST ROUSSEL VET, and user assumes the risk of any such use. HOECHST ROUSSEL VET MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF **FITNESS** FOR PARTICULAR PURPOSE Α OR MERCHANTABILITY. In no case shall HOECHST ROUSSEL VET be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale end warranty can be varied only by an agreement in writing signed by a duly authorized representative of HOECHST ROUSSEL VET.

Taktic[®] (amitraz) is registered trademark of Hoechst Veterinär GmbH.

The name and logo HOECHST are registered trademarks of HOECHST AG.

@1997 HRV 785205-2/97

MADE IN CANADA

Reference: EPA Stamped Accepted Label May 23, 1995; revised as par L. Dulak 5/30/97 e-mail plus amitraz RED. 970827d

Taktic®

EMULSIFIABLE CONCENTRATE MITICIDE/INSECTICIDE

FOR THE CONTROL OF TICKS, MANGE MITES AND LICE ON BEEF CATTLE, DAIRY CATTLE AND SWINE

DO NOT USE ON HORSES. MAY CAUSE FATAL COLON IMPACTION.

EPA Reg. No. 54382-3 EPA Est No. 045639-CAN-001 U.S. Patent Nos. 3,781,355 and 3,864, 497

Hoechst Roussel Vet

30 Independence Blvd. Warren, NJ 07059

Hoechst "

Hoechst Roussel Vet A member of the Hoechst Group

ACTIVE INGREDIENT: Amitraz (N'-(2,4-dimethylphenyl)-N-[[2,4-dimethylphenyl)imino]methyl]-N-methylmethanimidamide) INERT INGREDIENTS:

TOTAL

Percent by Weight

12.5 87.5 100.0

This product contains xylene-range solvents.

PRECAUCION AL USUARIO: Si usted no lee inglés, no use este producto hasta que la etiquata haya sido explicado ampilamente.

(TO THE USER: If you cannot read English, do not use this product until the label has been fully explained to you.)

KEEP OUT OF REACH OF CHILDREN DANGER-PELIGRO CAUTIONPRECAUCION

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PRECAUTIONARY STATEMENTS

Hazards to Humans (and Domestic Animais)

DANGER CAUTION

Causes eye damage. Do not get in eyes. Harmful if swallowed, inhaled or absorbed through skin. Repeated skin contact may cause an allergic reaction in certain individuals. Avoid breathing vapors or spray mists and avoid contact with skin or clothing.

Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Harmful if absorbed through ekin. Avoid contact with skin, eyes or clothing.

Causes moderate eye imitation.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear.

Long-sleeved shirt and long pants

Chemical-resistant footwear plus socks.

Chemical-resistant gloves

Goggles or face shield, and chemical-resistant apron when cleaning equipment, mixing or loading

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

For livestock spray or dip applications in enclosed areas: Apply only in well-ventilated areas.

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- Users should remove clothing immediately if pesticide gets inside.
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- Users should remove PPE immediately after handling this product.
 Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

During-mixing/loading-or application, wear a long-sleeved shirt and long pants. Wear chemical-resistant gloves, a hat, socke, boots, and goggles-or-face-shield. Mixer/loaders should also wear a chemical-resistant apron when handling the concentrated product. Wash thoroughly with seap and water after handling and before eating, urinating or smoking. Remove and wash clothing before rouse. Clothing-should be laundered separately from household articles. Replace gloves frequently. Clothing which has been drenched and used gloves should be disposed of in accordance with state or local regulation.

ENVIRONMENTAL HAZARDS

This product pesticide is toxic to fish and aquatic invertebrates. Do not epply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Drift and runoff from treated areas may be hazardous to fish aquatic organisms in adjacent

sites. Do not contaminate water by cleaning of equipment or disposal of equipment when disposing of equipment washwaters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

STORAGE: Not for storage in and around the home environment. Store in original container in a locked dry place. Do not open the container until ready to use. Use entire contents of can when opened. Keep from freezing.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or Environmental Control Ageny, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

in case of spillage, cover with an absorbent such as soda ash, clay or sawdust. Sweep up and dispose of as directed under Storage and Disposal.

DO NOT REUSE EMPTY CONTAINER.

EMERGENCY PHONE NOS.:

HUMAN, FIRE, SPILLS, ENVIRONMENTAL: 1-800-228-5635, Ext. 132

ANIMALS: 1-800-345-4735, Ext. 104

DIRECTIONS FOR USE

it is a violation of federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON HORSES or DOGS - CAN CAUSE DEATHS

DO NOT OPEN CONTAINER UNTIL READY TO USE.

USE TAKTIC® E.C. WITH WATER ONLY. DO NOT MIX WITH OIL OR OTHER SOLVENTS.

BEEF AND DAIRY CATTLE

TAKTIC® E.C. can be used on lactating dairy animals, with no withholding period for milk following application. Also, there is no posttreatment slaughter interval on beef and dairy cattle.

TICKS AND LICE:

TAKTIC® E.C. will control the following Ticks and Lice on cattle: Lone Star Tick (Ambiyomma americanum)

Gulf Coast Tick (A. maculatum)

Winter Tick (Dermacentor albipictus)

Brown Dog Tick (Rhipicephalus sanguineus)

American Dog Tick (D. variabilis)

Rocky Mountain Wood Tlck (Dermacentor anderson)

Spinose Ear Tick (Otoblus megnint)

Black-legged Tick (Ixodes scapularis)

Tropical Bont Tick (A. variegatum)

Cayenne Tick (A. cajennense)

Cattle Tick (Boophilus annulatus)

Southern Cattle Tick (B. microplus)

Biting Louse (Damalinia bovis)

Sucking Lice (Haematopinus eurystemus, Linognathus vituli, Scienopotes capillatus)

MITES

Scab and Mange Mites (Chorioptes bovis, Psoroptes ovis and Sarcoptes scablel var. bovis)

Spray:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. Use Taktic® solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off. For Lone Star ticks, cattle ticks, sucking lice and chewing lice, particular attention should be given to the legs, axilla and groin area, udder, tail regions and head, including the ears. For Gulf Coast ticks and ear ticks, treat the head, ears, shoulder area and neck with a low pressure spray. For control of lice, a second treatment 10-14 days later is recommended, to kill like hatching from eggs.

Spray Dip Machine:

For control of ticks and lice, mix one can (760 ml) of TAKTIC® E.C. in 100 gallons of water; for control of mites, mix one can of TAKTIC® E.C. in 50 gallons of water. To control cattle scables, applications should be made as instructed by USDA, APHIS, VS bulletins. Two treatments 7-10 days apart are required to control cattle scables. Use Taktic[®] solutions within 6 hours of mixing. Use up to 2 gallons of spray for a fully grown animal. It is important to wet the animal thoroughly and that the spray penetrates to the skin until run-off.

SWINE

MANGE MITE AND LOUSE (Sarcoptes scable) var. suis and Haematopinus suis);

IMPORTANT

Remove feed from pen and cover drinking bowls. Remove and destroy bedding. Hose out feces and excess feed. Use TAKTIC® solutions within 6 hours of mixing.

Spray

Mix one can (760 mi) TAKTIC® E.C. in 50 gallons of water (equivalent to 1/2 fl. ounce per gallon of spray solution). A sprayer with a coarse nozzle delivering the solution at 70 to 150 pai is recommended. Spray the walls, floor and any fittings in the pen. Spray all animals (at the same time) whether visibly affected or not. Spray the animals until the mixture runs off, paying particular attention to treat the jowl, legs, inside the ears and underside of the body. It is important that the spray penetrates to the skin until run-off. A second treatment is recommended to break the parasites' life cycles. Make the application 7-10 days after the first treatment for mite control, and 10-14 deys for lice control.

An alternate to spraying young pigs (piglets/weaners) is to dip them in a suitable-sized container. Dip 30 animals and then replace dip wash. Use dip wash to treat premises.

Do not treat animals more than 4 times per year.

Do not apply to swine within three days of slaughter.

Do not use Taktic[®] E.C. at the same time with any other amitraz containing product.

NET CONTENTS: 760 ml (25.7 fl. oz.)

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. HOECHST ROUSSEL VET warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions. or under conditions not reasonably foreseeable to HOECHST ROUSSEL VET, and user assumes the risk of any such use. HOECHST ROUSSEL VET MAKES NO OTHER WARRANTY. EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR Α PARTICULAR PURPOSE MERCHANTABILITY. In no case shall HOECHST ROUSSEL VET be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of HOECHST ROUSSEL VET.

Taktic® (amitraz) is registered trademark of Hoechst Veterinär GmbH. The name and logo HOECHST are registered trademarks of HOECHST AG.

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MADE IN CANADA

Reference: EPA Stamped Accepted Label May 23, 1995; revised as per L. Dulak 5/30/97 e-msil plus amitraz REO. 970827d

